EFFECT OF CBT ON PSYCHOLOGICAL MORBIDITY, QUALITY OF LIFE AND SLEEP DISTURBANCE IN WOMEN WITH POLYCYSTIC OVARIAN SYNDROME, PRE AND POST STUDY

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Submitted By

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DECLARATION BY THE CANDIDATE

I hereby declare that the dissertation entitled "**EFFECT OF CBT ON PSYCHOLOGICAL MORBIDITY, QUALITY OF LIFE AND SLEEP DISTURBANCE IN WOMEN WITH POLYCYSTIC OVARIAN SYNDROME, PRE AND POST STUDY**" submitted towards partial fulfillment of the requirements for the award of **M.PHIL in Clinical Psychology** degree to BFUHS is a compilation of original work carried out by me under the supervision of **Palak Upadhyay,** Assistant Professor, Department of Clinical Psychology, **Dr. Bholeshwar Prasad Mishra,** Professor & Head, Department of Clinical Psychology and **Dr. Pooja Tandon,** Professor, Department of Obstetrics & Gyanaecology. No part of this thesis has formed the basis for the award of any degree previously.

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Dedicated

to

my Family

&

Teachers

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Ms. Meitrai Mehta

ABBREVIATIONS

PCOS	Polycystic Ovarian Syndrome
QoL	Quality of Life
PCOS-QoL-E	Quality of Life- Emotional domain
PCOS-QoL-B	Quality of Life- Body image domain
PCOS-QoL-W	Quality of Life- Weight domain
PCOS-QoL-I	Quality of Life- Infertility domain
PCOS-QoL-M	Quality of Life- Menstrual disturbances domain
CBT	Cognitive Behavior Therapy
SES	Socioeconomic status

ABSTRACT

Introduction: Polycystic ovary syndrome (PCOS) is the most common multifaceted endocrine disorder with a spectrum of manifestations affecting women presenting with clinical, hormonal and psychological manifestation which significantly impact the quality of life (QoL) of women further contributing to psychological morbidity and sleep disturbances. CBT has been used in the treatment of aforementioned variables. Objectives of the study will be to evaluate the effect of CBT on QoL, psychiatric morbidity and sleep disturbances in women with PCOS.

Aim of Study: 1) To study the pre and post effect of CBT on psychological morbidity in women with PCOS. 2) To study the pre and post effect of CBT on Quality of Life in women with PCOS. 3) To study the pre and post effect of Sleep disturbances in women with PCOS

Materials & methods: Study will be conducted on 30 patients diagnosed with PCOS, admitted in Obstetrics and Gynaecology ward or visiting Obstetrics and gynaecology OPD at DMC&H. They will be required to fill HDRS, HARS, PSQI & POCS-QOL pre and post intervention.

Results: There was a significantly greater reduction in psychological morbidity and sleep disturbances leading to improvement in Quality of Life in patients with PCOS post CBT intervention. The findings showed positive results across all the domains of PCOS-QoL. Findings revealed statistically different scores across psychological morbidity, sleep quality as well as emotional concerns and body image domain attributed to QoL at follow up.

Conclusion: The study will contribute to efficacious treatment of PCOS using cognitive behavioural approaches by working on the psychological aspects leading to the development of PCOS.

Keywords: Polycystic ovary syndrome, cognitive behavioural therapy, intervention, depression, anxiety, quality of life, sleep disturbance, insomnia, psychological morbidity.

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KEY TO MASTER CHART

HDRS-PRE: HAMILTON DEPRESSION RATING SCALE PRE INTERVENTION

HDRS-POST: HAMILTON DEPRESSION RATING SCALE POST INTERVENTION

HDRS-FU: HAMILTON DEPRESSION RATING SCALE FOLLOW UP

HARS-PRE: HAMILTON ANXIETY RATING SCALE PRE INTERVENTION

HARS-POST: HAMILTON ANXIETY RATING SCALE POST INTERVENTION

HARS-FU: HAMILTON ANXIETY RATING SCALE FOLLOW UP

PSQI-PRE: PITTSBURG SLEEP QUALITY INDEX PRE INTERVENTION

PSQI-POST: PITTSBURG SLEEP QUALITY INDEX POST INTERVENTION

PSQI-FU: PITTSBURG SLEEP QUALITY INDEX FOLLOW UP

E-PRE: POLY CYSTIC OVARIAN SYNDROME QUALITY OF LIFE EMOTIONAL DOMAIN PRE INTERVENTION

E-POST: POLY CYSTIC OVARIAN SYNDROME QUALITY OF LIFE EMOTIONAL DOMAIN POST INTERVENTION

E-FU: POLY CYSTIC OVARIAN SYNDROME QUALITY OF LIFE EMOTIONAL DOMAIN FOLLOW UP

B-PRE: POLY CYSTIC OVARIAN SYNDROME QUALITY OF LIFE BODY IMAGE DOMAIN PRE INTERVENTION

B-POST: POLY CYSTIC OVARIAN SYNDROME QUALITY OF LIFE BODY IMAGE DOMAIN POST INTERVENTION

B-FU: POLY CYSTIC OVARIAN SYNDROME QUALITY OF LIFE BODY IMAGE DOMAIN FOLLOW UP

W-PRE: POLY CYSTIC OVARIAN SYNDROME QUALITY OF LIFE WEIGHT DOMAIN PRE INTERVENTION

W-POST: POLY CYSTIC OVARIAN SYNDROME QUALITY OF LIFE WEIGHT DOMAIN POST INTERVENTION

W-FU: POLY CYSTIC OVARIAN SYNDROME QUALITY OF LIFE WEIGHT DOMAIN FOLLOW UP

I-PRE: POLY CYSTIC OVARIAN SYNDROME QUALITY OF LIFE INFERTILITY DOMAIN PRE INTERVENTION

I-POST: POLY CYSTIC OVARIAN SYNDROME QUALITY OF LIFE INFERTILITY DOMAIN POST INTERVENTION

I-FU: POLY CYSTIC OVARIAN SYNDROME QUALITY OF LIFE INFERTILITY DOMAIN FOLLOW UP

M-PRE: POLY CYSTIC OVARIAN SYNDROME QUALITY OF LIFE MENSTRUAL DISTURBANCES DOMAIN PRE INTERVENTION

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M-FU: POLY CYSTIC OVARIAN SYNDROME QUALITY OF LIFE MENSTRUAL DISTURBANCES DOMAIN FOLLOW UP

PCOS-QoL PRE: POLY CYSTIC OVARIAN SYNDROME QUALITY OF LIFE PRE INTERVENTION

PCOS-QoL POST: POLY CYSTIC OVARIAN SYNDROME QUALITY OF LIFE POST INTERVENTION

PCOS-QoL FU: POLY CYSTIC OVARIAN SYNDROME QUALITY OF LIFE FOLLOW UP

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INTRODUCTION

Polycystic ovarian syndrome is a heterogeneous endocrine disorder characterized by the presence of ovarian cysts, anovulation, and endocrine disruption, which has major adverse effect on the quality of a woman's life. PCOS mainly affects 8-13 percent of all women of reproductive age.[1] The symptoms of PCOS and their distribution within the same patient pattern differ substantially from one woman to the next. These complaints include amenorrhea, irregular amenorrhea, oligomenorrhea, menorrhagia, hirsutism, or infertility, anovulation, instant susceptibility to vulgaris, androgenic alopecia, insulin insensitivity weight gain, acne and close androgen production. The global prevalence of PCOS ranges from 4% to 20% depending on the population researched and the PCOS features used for diqgnosis. PCOS prevalence in India is determined to be 3.7–22.5%.[2]

The definition provided by the WHO is consistent with the viewpoint that health is multifaceted. In order to manage the whole range of symptoms and potential consequences associated with PCOS, women must also address the psychological and social aspects of their lives with managing the physical symptoms where PCOS as a disease to be the result of organ failure in the body's endocrine systems including adrenals, ovaries, pituitary, adipocytes and endocrine pancreas.[3] Comorbidities related to reproduction (infertility, pregnancy difficulties), metabolism (T2DM) and cardiovascular disease (CVD), and psychology (anxiety, depression, low Quality of life (QoL) are all likely to be present in females with PCOS.[4]

As PCOS is regarded as an enormous multifaceted endocrine illness and has a broad clinical presentation. Amongst the many symptoms the implications of androgen excess have been emphasized where it may manifest as hirsutism [5] and acne in upto 15%–30% of adult women [6] or infertility, being another key sign amongst approximately 80% of females with PCOS where more than 90-95% coming to a

fertility centre are anovulatory having normal primordial follicle counts while having significantly increased primary and secondary follicle numbers.[7] Some deranged factors involved in normal follicular development impede further follicular growth of the follicles after reaching a diameter of 4-8 mm. Failure of ovulation to occur then leads to infertility as no dominant follicle develops. Individuals diagnosed with PCOS have a greater likelihood of being obese than those without PCOS. Moreover, obesity and a higher risk of anxiety as well as depression are linked.[4] For those diagnosed with PCOS, anxiety, depression, and obesity can combine to cause a significant decline in QoL.

DIAGNOSTIC CRITERIA FOR PCOS

The diagnostic criteria for PCOS have changed countless times and no universally accepted version exists. The NIH criteria require hyperandrogenism (HA) and chronic oligo/anovulation or ovulatory dysfunction (OD) to be present.[8]

The Rotterdam criteria contain polycystic ovarian morphology (PCOM) and demand at least 2 out of these 3 key reproductive traits, leading to three different affected phenotypes:

1. **NIH PCOS** also known as Hyperandrogenism with ovulatory dysfunction, with or without polycystic ovarian morphology.
2. **Hyperandrogenism and polycystic ovary morphology** (non-NIH Rotterdam types)
3. **Ovulatory Dysfunction** (non-NIH Rotterdam types)

   The diagnostic criteria for Polycystic Ovary Morphology (PCOM) given by the Rotterdam group defined it as presence of 12 or more follicles measuring 2 to 9 mm in diameter and/or an ovarian volume of greater than 10 cm3. This presentation in one ovary sufficiently defines the polycystic ovary.[9]

An independent panel elaborated upon the evidence in an international workshop through 2012 and recommended that Rotterdam criteria to

be adopted with specific identification of phenotype, as listed [10], below in order of decreasing clinical severity and then decreasing specificity of milder phenotypes.

1. **Phenotype 1** is classic syndrome combination having all reproductive endocrine features like hyperandrogenism, oligo-anovulation, PCOM.
2. **Phenotype 2** is the combination of hyperandrogenism and oligo-anovulation (the essential NIH criteria).
3. **Phenotype 3** is including hyperandrogenism and PCOM without infertility hence it referred to as ovulatory PCOS as endorsed by AE-PCOS.
4. **Phenotype 4** is the combination of oligo-anovulation and PCOM (non-hyperandrogenic PCOS).

As per Rosenfield, 2016 [11], The adult and adolescent criteria for diagnosis had been categorised separately as the following:

Adult Diagnostic Criteria (Rotterdam) [9]

Otherwise unexplained alternative phenotypes:

1. Phenotype 1 (classic PCOS)

a. Clinical and/or biochemical evidence of hyperandrogenis
b. Evidence of oligo-anovulation
c. Ultrasonographic evidence of a polycystic ovary

2. Phenotype 2 (Essential NIH Criteria)

a. Clinical and/or biochemical evidence of hyperandrogenism
b. Evidence of oligo-anovulation

3. Phenotype 3 (ovulatory PCOS)

a. Clinical and/or biochemical evidence of hyperandrogenism
b. Ultrasonographic evidence of a polycystic ovary

4. Phenotype 4 (nonhyperandrogenic PCOS)

a. Evidence of oligo-anovulation
b. Ultrasonographic evidence of a polycystic ovary

Adolescent Diagnostic Criteria [9]

Otherwise unexplained combination of:

1. Abnormal uterine bleeding pattern

a. Abnormal for age or gynecologic age

b. Persistent symptoms for 1–2 years

2. Evidence of hyperandrogenism

a. Consistently high levels of testosterone, measured by a reliable lab, provide the most reliable indication.

b. Moderate-severe hirsutism as a clinical evidence of hyperandrogenism

In December 2012, the Evidence-based Methodology Workshop on PCOS held at NIH recommended continued usage of broad, inductive Rotterdam criteria, with identification of PCOS phenotypes.[12] However, it did not consider hyperandrogenism as a necessity for diagnosis.[13]

The diagnosis of PCOS using Rotterdam and AES criteria depends on having an adequate definition of PCOM. The Androgen Excess and PCOS Society (AE-PCOS) recommends that the diagnosis needs to be made when there is hyperandrogenism either with irregular menstruation or PCOM where menstrual disturbances include Oligomenorrhoea (menses every 6 weeks to 6 months); or amenorrhoea (menses greater than every six months apart or absence), dysfunctional uterine bleeding in association with anovulation by appropriate timed luteal phase and plasma progesterone levels.[7]

THEORETICAL BACKGROUND

Leventhal's [14] common sense model of self-regulation

It underscores five major aspects about disease:

1) Disease identity: Perceived symptoms associated with the disease;

2) Disease chronology: Perceived chronicity and cyclicity around the disease;

3) Disease consequences: perceived impact of the disease;

4) Disease control: perceived personal control and therapeutic control over the disease; and

5) Cause of the disease: Perceived cause(s) of the disease.

The model explains that how well someone deals with a disease depends on a balanced and steady system of self-regulation involving how they perceive the illness (thinking about it), how they feel about it (emotionally), how individuals can cope with it & how they assess it over time. The emotional part of this process involves how people manage their feelings, cope with health concerns, and understand the risks involved. Also, feeling of having control over the situation is really important and affects many outcomes, including how stressed you feel. Coping with problems directly and altering how you think about them can help manage this stress. Initial studies indicate that focusing on individuals' perceptions of their condition could play a crucial role in modifying their behavior and enhancing the QoL for females diagnosed with PCOS.[8]

Role of Anti- Mullerian hormone (AMH)

According to this theory, a female foetus exposed to environmental influences, while still in utero is more likely to develop insulin resistance, hyperandrogenism, and polycystic ovaries as an adult. It is still unknown which environmental elements affect the developing foetus and how exposure occurs~~,~~ Literature suggest that a female foetus may be genetically predisposed to develop PCOS later in life if she is exposed to excessive amounts of androgens during pregnancy.[15]

In addition to the three diagnostic criteria, anti-mullerian hormone (AMH) is a prominent hormonal indication that plays a key role in the formation and maturation of ovarian follicles in women with PCOS.[16] It is postulated that the placenta's activity of aromatase P450 is inhibited by elevated levels of circulating maternal AMH in PCOS, allowing testosterone to pass through the placenta. Elevated levels of maternal circulating testosterone in conjunction with reduced aromatase activity facilitates enhanced placental transit and increases the foetus's exposure to androgens by making the maternal testosterone work on foetal ovaries, as soon as they become functional at about 36 weeks of gestation, "programming" them to recruit more preantral follicles and hence produce higher levels of AMH. In response, this tall AMH concentrations in PCOS appear to extend luteinizing hormone discharge, repress follicle invigorating hormone activity on aromatase, resulting in hyperandrogenic environment of grown-up PCOS, [17] where over discharge of AMH prevent the follicular advancement leading to ovarian breakdown.

Dysbiosis of Intestine Microbiota [18]

The relationship between dysbiosis of intestinal microbiota (imbalance in gut bacteria composition) and polycystic ovary syndrome (PCOS) is an emerging area of research that underscores the potential impact of gut health on reproductive and metabolic disorders. Understanding this connection is important for elucidating novel therapeutic approaches and lifestyle interventions for managing PCOS. The theory regarding the etiology of PCOS suggests that disruptions in gut bacteria ("Intestinal Microbiota Dysbiosis") caused by a poor diet lead to greater permeability of the intestinal mucosa. This leads to increased levels of lipopolysaccharide (LPS) from Gram-negative colonic bacteria entering the bloodstream. This activation of the immune system affects insult receptor function, raising serum insult levels. Consequently, the ovaries produce more androgens, disrupting normal follicle development. The gut microbiota plays a crucial role in regulating metabolism through the

fermentation of dietary fibers, production of short-chain fatty acids (SCFAs), and modulation of energy extraction from food.

Gut microbiota metabolites, such as SCFAs, bile acids, and lipopolysaccharides, can influence hormonal signaling pathways relevant to PCOS. It is often accompanied by metabolic comorbidities such as obesity and dyslipidemia. Dysbiosis of the intestinal microbiota has been implicated in the development and progression of these metabolic disturbances. Modulating gut microbiota composition through dietary interventions or probiotic supplementation thus may have beneficial effects on metabolic health in PCOS.

Targeting gut microbiota composition and function represents a promising therapeutic approach for managing PCOS-related symptoms. Strategies such as probiotics, prebiotics, dietary fiber supplementation, and personalized nutrition interventions aim to restore gut microbial balance and improve metabolic outcomes in women with PCOS.

Therefore, as the dysbiosis of intestinal microbiota is intricately linked to the pathophysiology of PCOS, contributing to metabolic dysfunction, inflammation, and hormonal dysregulation, the Intestinal Microbiota Dysbiosis hypothesis of PCOS can explain all three components of the syndrome: anovulation/menstrual irregularities, hyperandrogenism (acne, hirsutism), and the production of multiple small ovarian cysts.[18]

PSYCHOSOCIAL ASPECTS OF PCOS

Quality of life

In the context of healthcare, Quality of Life (QOL) is considered a measure of disease type and treatment outcome. The term 'Quality of life' encompasses various parameters that differ among individuals, including standard of living, living conditions, fulfilment of life's needs,

physical well-being, mental health, and levels of satisfaction. In medical contexts, QOL often refers to the extent to which an individual can manage their activities of daily living and experience a sense of well-being. Therefore, QOL broadly includes the fulfilment of needs, sense of well-being, and conditions of functioning, among other aspects of material and mental life that contribute to an individual's overall satisfaction, well-being, and happiness.

QOL as a general concept has been defined based on subjective experiences and individual perception. It encompasses all essential conditions for a contented life.[19] QOL has been also elaborated as the satisfaction and happiness of an individual with their life where the comprehensive concept of QOL combines objective material criteria with subjective behavioural aspects.[20] This approach emphasizes objective material conditions, life opportunities, and their determinants as essential for people to effectively use their resources to fulfill their needs. In contrast, the capability approach defines QOL in terms of a person's capability to achieve certain functioning, ranging from basic to complex, with the individual having the freedom to choose among various functioning.[21]

The World Health Organization's (WHO) [22] comprehensive definition of health emphasizes the holistic nature of well-being, extending beyond the absence of disease to encompass physical, mental, and social dimensions. This understanding resonates with the concept of quality of life (QoL) as articulated by WHO in 1995, which highlights integration of physical health, mental well-being, social interactions, independence, and environmental factors into a multifaceted construct.

In the context of polycystic ovary syndrome (PCOS), a condition with substantial physical and psychological implications, the impact on patients' QoL becomes evident. Patients with PCOS often report compromised physical health due to symptoms such as irregular menstruation, infertility, and metabolic disturbances.[23] Concurrently,

the syndrome can exert profound psychological effects, impacting mental well-being, body image, and social relationships. Furthermore, PCOS can challenge individuals' sense of independence and their ability to navigate societal expectations and personal goals, highlighting the intersection of health and QoL. By embracing WHO's holistic framework, future studies can more comprehensively assess and address the multifaceted challenges faced by individuals with PCOS, ultimately striving to enhance their overall well-being and quality of life. Despite a growing global awareness of this issue, perspectives from specific regions, such as India, remain underexplored. It is thus emphasised that health and healthcare assessments should incorporate an evaluation of well-being, which can be measured by improvements in the quality of life (QOL) related to the health of the individual where many symptoms of PCOS are associated with mental stress, and some may exacerbate pre-existing conditions into mental disorders, highlighting the importance of considering dysfunction associated with PCOS in this context.

Psychological Morbidity

When a mental or psychological illness leads to both physical and psychological deterioration, it is commonly referred to as psychological morbidity.[24] This term typically applies to individuals who, despite experiencing mental decline, remain keenly aware of their situation. "Psychological morbidity" and "psychological illness" are mostly used inspite of the broader term "psychosocial problem." As per the World Health Organization (WHO) [22], factors inclusive of the duration of a disease, its nature, and the number of affected individuals are used to assess morbidity itself Consequently, the term also denotes the prevalence of mental illnesses within a specific social group.

Depression

Depressed mood, characterized by persistent feelings of subjective sadness is a key feature of depressive episode across varying severity levels (mild, moderate, and severe). In addition to depressed mood, individuals typically experience loss of interest and pleasure, decreased energy leading to increased fatigue and reduced activity levels. Severe fatigue following minimal exertion is common. Other frequent symptoms include challenges with focus and reduced self-confidence, feelings of guilt and worthlessness, pessimistic views about the future, thoughts or actions of self-harm or suicide, sleep disturbances, and decreased appetite. For a diagnosis of a major depressive episode, such symptoms typically persist for atleast a period of 2 weeks, although shorter durations may be considered if symptoms are particularly severe and rapid in onset.

The literature suggests a concerning relationship between polycystic ovary syndrome (PCOS) and increased risk of mental health conditions, particularly major depression [25], which in turn can contribute to elevated rates of suicide attempts among affected individuals.

Studies indicate that up to 6.5% of people with PCOS experience major depression, highlighting a significant psychological burden associated with this condition [26] The psychological burden of living with PCOS, compounded by the challenges of managing associated health issues, can exacerbate feelings of hopelessness and distress.

Additionally, depressive disorders are recognized as a primary cause of disability globally, encompassing a range of symptoms that can profoundly impact daily functioning and overall well-being. The presence of PCOS appears to amplify the risk of developing these debilitating mental health conditions over a person's lifetime, potentially due to the complex interplay between hormonal imbalances, physical

symptoms, and psychosocial stressors associated with the syndrome. The implications of such findings are profound, highlighting the urgent need for comprehensive mental health screening and support for individuals with PCOS. By addressing the mental health aspects of this condition, including the heightened risk of major depression and subsequent suicide attempts, healthcare providers can better mitigate the substantial burden faced by affected individuals and promote holistic approaches to care that encompass both physical and psychological well-being.

Anxiety

In specific circumstances, experiencing a certain level of anxiety is normal and can also be beneficial, motivating individuals to take action when facing challenges to avoid harm or failure. Anxiety plays a critical role in human survival; for instance, during the fight-or-flight response, it prepares the body in responding to danger and ensure survival. The nervous system is central to the anxiety process. When the brain perceives a threat, it triggers the autonomic nervous system, which stimulates the production of stress hormones by glands and other organs, leading to a physiological response to the perceived threat. This response includes an increased heart rate and suppression of certain bodily functions like digestion, reallocating resources for necessary actions during times of perceived threat or stress. Once the situation is resolved, the parasympathetic nervous system activates to restore normal bodily functions and energy levels.[27] People experience anxiety for various reasons in their lives. Promptly addressing these symptoms usually prevents harm. However, if anxiety symptoms persist for an extended period and are severe, they can significantly impact an individual's overall well-being.

Polycystic ovary syndrome (PCOS) is intricately connected to anxiety disorders, manifesting through complex physiological and psychological pathways. PCOS is characterized by hormonal

imbalances, including elevated levels of androgens (e.g., testosterone) and insulin resistance.[28] These hormonal disturbances can disrupt neuroendocrine pathways implicated in mood regulation and stress response, potentially predisposing individuals to anxiety disorders. The challenges associated with PCOS, such as irregular menstrual cycles, infertility concerns, hirsutism, and weight fluctuations, can contribute to significant psychosocial stress.[29] Coping with these symptoms and their impact on body image, self-esteem, and social interactions may exacerbate anxiety symptoms.[30-32]

PCOS, considered a metabolic syndrome, affects the body's metabolism and can cause chemical imbalances. Several researchers have suggested biological mechanisms such as elevated male hormone levels (hyper-androgenism) and insulin resistance [33] links PCOS symptoms to anxiety and depressive symptoms.

Inflammatory markers such as C-reactive protein (CRP) and pro-inflammatory cytokines have been implicated in the pathophysiology of both PCOS and anxiety.[34]

Literature indicate that women with PCOS have a four-fold increased risk of developing depressive symptoms and a six-fold increased risk of developing anxiety symptoms compared to those without PCOS [35]. This is partly attributed to PCOS itself representing a stressful factor by increasing rates of anxiety and depression. Therefore, both international and Indian guidelines recommend assessing psychological factors and conducting routine screening for anxiety and depression in all women with PCOS.

Sleep disturbances

PCOS is closely associated with sleep disturbances, contributing to significant disruptions in sleep quality and patterns among affected individuals. Sleep disruptions are frequently observed in women with

PCOS, more likely due to disruption in metabolic characteristic of the condition. PCOS is characterized by hormonal imbalances, including elevated androgen levels and insulin resistance, which can disrupt the body's natural circadian rhythm.[36]

Dysregulation of key hormones such as melatonin, which regulates sleep-wake cycles, may contribute to difficulties in falling asleep and maintaining restful sleep. Both excessive daytime sleepiness (hypersomnia) and problems getting or staying asleep are usual sleep disorders in PCOS, with significantly increased frequency as compared to women without PCOS.[37] It is often associated with metabolic abnormalities such as insulin resistance and dyslipidemia, which have been linked to restless leg syndrome where restless legs syndrome is characterized by uncomfortable sensations in the legs during rest, leading to an irresistible urge to move the legs and disrupting sleep. Other sleep disorder correlated further with PCOS include presence of chronic insomnia, a common sleep issue in PCOS, is linked to symptoms such as severe daytime sleepiness, difficulties with attention, fatigue, memory problems and concentration.[38]

Many individuals with PCOS are overweight, and this excess weight can lead to obstructive sleep apnea (OSA) where OSA is characterized by repeated pauses in breathing during sleep due to airway obstruction, leading to daytime fatigue.[39] Females with PCOS commonly experience sleep problems such as concerns with falling asleep, poor sleep quality, restlessness during the night, severe fatigue, sleepwalking, nightmares, and restless leg -movements and disruptions in their sleep patterns.[40] Research suggests that women in their 30s with PCOS may experience twice the rate of sleep disturbances compared to their peers without PCOS.[41] The exact reasons for this correlation are not completely understood. Research indicates that the prevalence of sleep disturbances could be approximately 20% greater in women with PCOS in comparison of those without.[29]

The psychological impact of PCOS, including increased prevalence of anxiety and depression, can contribute to insomnia and other sleep disorders. Heightened stress levels, worries related to infertility or body image, and mood disturbances can disrupt sleep initiation and maintenance These sleep-related problems can significantly affect social functioning and overall quality of life for individuals with PCOS. Recognizing the prevalence and impact of disturbances in sleep in PCOS is crucial for developing better management strategies and improving the well-being of affected individuals.

SYMPTOMS OF PCOS AND ITS PSYCHOLOGICAL CORRELATES

Obesity and PCOS

The relationship between polycystic ovary syndrome (PCOS) and obesity is significant and bidirectional, with each condition influencing and exacerbating the other. This complex interplay underscores the importance of addressing both PCOS and obesity comprehensively to improve health outcomes and quality of life for affected individuals. In women predisposed to PCOS, metabolic and hormonal dysregulation such as insulin resistance and hyperandrogenism can lead to weight gain and eventually obesity.[42] Obesity, in turn, can exacerbate PCOS symptoms by further disrupting metabolic function and reproductive health. Those affected by PCOS often encounter numerous appearance-related challenges attributes to weight and report higher levels of body image dissatisfaction compared to healthy individuals. Additionally, it has been suggested that imbalanced hormone levels, along with obesity and negative body image, contribute further in the development of severe depression in a substantial portion (40–45%) of women diagnosed with PCOS.[43]

Obesity is highly prevalent among women with PCOS, with estimates suggesting that up to 50-60% of women with PCOS are overweight. [44] Conversely, women with obesity are at a higher risk of developing

PCOS due to insulin resistance and hormonal dysregulation associated with excess adiposity.

Both PCOS and obesity are characterized by insulin resistance, a condition where cells become less responsive to insulin, leading to compensatory hyperinsulinemia (elevated insulin levels). Insulin resistance contributes to pathogenesis of PCOS by stimulating ovarian androgen production and impairing ovulatory function. Obesity-related hormonal changes, such as elevated circulating levels of estrogen and leptin, can exacerbate hormonal imbalances seen in PCOS, including hyperandrogenism (elevated androgen levels) and irregular menstrual cycles.[45] These hormonal disturbances contribute to the clinical manifestations of PCOS, such as hirsutism, acne, and infertility. Managing PCOS in the context of obesity presents unique challenges due to the intertwined nature of these conditions.

Womanhood and PCOS [38]

Studies indicate that menstrual irregularities and fertility issues elevate the risk of distress in psychological domain resulting in cognitively distorted perception of womanhood as evidenced by thematic analysis uncovering prevalent narratives of feeling "abnormal," "freakish," and inadequate as women. Based on subjective accounts found in literature, women with PCOS struggle to adhere to societal norms concerning appearance, leading to a compromised sense of femininity. It has been further concluded that women with PCOS often have a unique perspective on their experience of femininity [36] and express feeling less feminine and distinct from their peers.[54] The ability to conceive, regular menstrual cycles, and smooth, hairless faces were related with femininity. Women experiencing these symptoms expressed feeling less "feminine" and "different" from others, leading to the perception of PCOS as an affront to womanhood. These feelings were linked to three common symptoms experienced by women with PCOS, namely, infertility, irregular or absent periods and excessive

hair growth. This suggests that PCOS is a highly stigmatizing condition that impacts women's sense of femininity, regardless of their adherence to traditional notions of womanhood.

Psychopathology associated with PCOS has been linked to its "masculinizing" symptoms.[38] It is suggested that the psychological impact of PCOS, particularly on body image, contributes to higher level of psychological morbidity. Adding further, due to the clinical aspects and potential medical complications of PCOS, affected women also contend with disruptions to their sense of womanhood, exacerbated by feelings of shame often related with physical changes that diverge from prevailing standards of attractiveness (such as hirsutism, obesity, acne, and alopecia). Affective changes and increased stress levels are attributed to various environmental, genetic, and hormonal factors affecting women's mental well-being.

Hair growth

PCOS is characterized by hyperandrogenism, which refers to elevated levels of androgens (male hormones) such as testosterone and dihydrotestosterone (DHT). Genetic susceptibility also influences the development of hirsutism in PCOS with certain genetic variations affecting androgen metabolism and sensitivity of hair follicles to androgens. Excessive androgen production by the ovaries and adrenal glands in women with PCOS can lead to the development of hirsutism[46] which is defined as the excessive growth of hair in a male pattern in women Androgens stimulate the growth of terminal hair (thick, pigmented hair) in areas typically associated with male pattern hair growth, such as the face (upper lip, chin), chest, abdomen, and back. Excessive hair growth ranks as the second most distressing symptom for women with PCOS, significantly impacting their quality of life.[47] Studies indicate that increased hair growth, especially in visible areas like the face, fosters a perception of masculinity among affected women which often lead to employment of masculine terminology (e.g.,

beard, mustache) to describe themselves and view their bodies as falling short of feminine ideals.[48]

Furthermore, insulin resistance is a common metabolic feature of PCOS, which plays a role in exacerbating androgen excess and hirsutism. Insulin resistance leads to increased insulin levels, which in turn stimulate ovarian androgen production and decrease the production of sex hormone-binding globulin (SHBG).[49] Lower SHBG levels result in increased levels of free circulating androgens, contributing to hirsutism.

Hirsutism can have a significant impact on a woman's quality of life, affecting self-esteem, body image, and social interactions. Women with PCOS-related hirsutism may experience distress and emotional burden due to perceived stigma and societal beauty standards.

Infertility and sexual life

Among the most distressing reproductive concerns for women with PCOS is the heightened risk of pregnancy loss, with approximately one-third of pregnancies ending in spontaneous abortion—a rate double that of women without PCOS upto ranging 12–15%.[50] The inability to conceive and carry a pregnancy can evoke feelings of abnormality and shame, influencing women's perceptions of femininity and identity.[51] Additionally, a majority of women with PCOS experience anovulation, leading to infertility and irregular menstrual cycles. Prolonged exposure to unopposed estrogen can lead to endometrial hyperplasia, heightening further the risk of development of medical conditions such as cancer. PCOS detrimentally affects women's sexual functioning and satisfaction, often resulting in lower sexual contentment compared to female participants without PCOS.[52] Individuals with PCOS also tend to perceive themselves as less sexually desirable and report lower overall sexual satisfaction, which can profoundly impact self-esteem and female identity which may lead

to social stigma and the development of significant psychopathology later in life. These reproductive challenges underscore the profound impact of PCOS on women's reproductive health and overall well-being.

Eating disorder

The association between PCOS and eating disorders, notably bulimia, has been observed, with body image dissatisfaction playing a significant role in their development. The physiological mechanism in PCOS patients highlights a decreased release of cholecystokinin, a hormone which induces feelings of fullness.[53] These hormonal disturbances of inadequate levels of cholecystokinin can affect appetite regulation and satiety signals, potentially leading to disordered eating behaviors such as emotional eating, binge eating, or restrictive eating patterns.

Other hormonal imbalances recognized in PCOS are characterized by hyperandrogenism and insulin resistance.[54] Insulin resistance, a hallmark of PCOS, can contribute to dysregulated glucose metabolism and fluctuations in blood sugar levels. This metabolic dysfunction may influence cravings for high-sugar or high-calorie foods, contributing to maladaptive eating behaviors.

The relationship between eating disorders and polycystic ovary syndrome (PCOS) is a complex and clinically significant association that involves both psychological and physiological factors. Women with PCOS often experience challenges related to body image due to symptoms such as weight gain, hirsutism (excessive hair growth), and acne. These physical manifestations of PCOS can contribute to negative body image perceptions and psychological distress, which may predispose individuals to developing eating disorders.[55]
Women with PCOS are at increased risk of mood disorders such as depression and anxiety. These mental health conditions can be both a

cause and consequence of disordered eating behaviors, forming a complex interplay with PCOS-related symptoms.

Recognizing the association between PCOS and eating disorders is crucial for healthcare providers involved in the care of affected individuals.[56] Screening for eating disorder symptoms should be part of routine assessments for women with PCOS, and integrated treatment approaches addressing both the metabolic and psychological aspects of PCOS and eating disorders are recommended. Understanding this relationship is essential for optimizing the management and treatment of women with PCOS who may be at risk for or affected by eating disorders.

Psychopathology

Since estrogen is believed to play a role in modulating psychological symptoms, it is hypothesized that a decrease in estrogenic effects in PCOS may add on to their onset where as a result, extended exposure to elevated estrogen levels due to anovulation in PCOS may increase the susceptibility of women to psychosis. Importantly, women with PCOS exhibit a higher occurrence of severe mental disorders like schizophrenia.[57] Findings indicates that women members with PCOS face an elevated risk of experiencing psychological distress and are more prone to various independent psychiatric disorders. Specifically, the prevalence rates are approximately 5% for obsessive-compulsive disorder (OCD), 5% for social phobia, 4% for panic disorder, 34% to 57% for anxiety, and 28% to 64% for depression.[58]

Risk Factors

Few risk factors identified which contribute to the development of PCOS in adults include history of type 1 and type 2 diabetes, gestational diabetes and insulin resistance, where it has been found to affects a significant proportion (50%–70%) of women with PCOS [59],

and is identified to be a major contributor to various associated conditions such as hypertension, dyslipidemia, metabolic syndrome and glucose intolerance.

Additionally, as PCOS is acknowledged as a hereditary condition, as evidenced by its familial clustering, a family history of PCOS is identified to be a significant risk factor. The prevalence of PCOS or its features among first-degree relatives underscores genetic influences, with higher concordance observed in monozygotic twins compared to dizygotic twins.[60] Genome-wide association studies (GWAS) among Han Chinese have identified particular genetic loci associated with PCOS susceptibility [61], with some findings replicated in European populations. Notably, the genetic overlap suggests an ancient origin of PCOS predating human migration out of Africa.[62]

In childhood, several factors serve as potential precursors to PCOS development where prenatal factors associated with PCOS include higher birth weight in girls born to overweight mothers, congenital virilization, and lower birth weight.[63] Risk factors that become evident later in childhood include early onset of pubic hair growth (premature pubarche), atypical early puberty (central precocious puberty), obesity syndromes, skin changes like acanthosis nigricans, and metabolic syndrome.[64] These risk factors collectively contribute to the understanding of the complex etiology and pathogenesis of PCOS, highlighting the interplay between genetic predisposition and environmental influences across the lifespan drawing attention to early detection and management of risk factors in PCOS as essential, particularly as women with PCOS frequently seek medical attention early in their reproductive years.[65]

PHARMACOLOGICAL TREATMENT FOR PCOS

The treatment selected for women with PCOS is determined by their specific symptoms, which usually fall into the three main categories

namely, menstruation-related disorders, androgen-related symptoms, and infertility. Metformin and thiazolidinediones are medications with insulin-lowering effects that improve insulin sensitivity, thereby decreasing circulating androgen levels.[66] These medications are important in the treatment intervention of PCOS because women with this condition have a higher risk of insulin resistance, which can contribute to metabolic disorders and cardiovascular disease.

PCOS and Obesity: Obesity has been related to hypothalamic-pituitary-ovarian axis, dysfunctional in nature, potentially resulting in the development of PCOS. Hyperinsulinemia is associated with obesity exacerbates lipid profiles and glucose intolerance in PCOS patients.[67] Obesity promotes the production of androgens through LH stimulation, resulting in hyperandrogenism. Leptin, an appetite-regulating adipokine, affects the neuroendocrine and reproductive systems of obese PCOS women, potentially impeding ovarian follicular development.[68]

Anti-androgens: Drugs such as spironolactone, flutamide, and cyproterone acetate are preferred for initial treatment of hirsutism as they reduce androgen secretion by inhibiting androgen receptors. Spironolactone and finasteride are also used to manage symptoms of androgen excess.[69] Infertility treatment options include clomiphene, laparoscopic ovarian drilling, gonadotropins, and assisted reproductive technology. Literature suggests that letrozole and metformin may plays a crucial role in inducing ovulation.[70] Tamoxifen, similar to clomiphene, is used to treat anovulation in patients unresponsive to or failing clomiphene citrate. Letrozole offers advantages over clomiphene citrate as it does not deplete estrogen receptors or have an antiestrogenic effect on the endometrium, making it a preferable alternative for inducing ovulation.[71] Gonadotropins such as recombinant FSH and HMG are second-line treatments for inducing ovulation.[72] Laparoscopic surgery and in vitro fertilization are considered second- and third-line treatments, respectively, for infertility in PCOS women.[73]

Oral Contraceptives (OCPs): OCPs are divided into progesterone-only pills and combined pills containing estrogen and progesterone [74,75] They are first-line therapy for women who do not want to ovulate and are experiencing menstrual irregularities. insulin resistance is not affected by OCPs but may result in metabolic disturbances, so their usage should be carefully monitored.[76]

Lifestyle Intervention: Lifestyle modification is crucial for managing PCOS, particularly in overweight women who are at greater risk of comorbidities like type II diabetes.[77] Studies show that alteration in exercise, attitude and diet, positively impact body weight, testosterone levels and insulin resistance.[78,79] Weight loss through lifestyle management improves abdominal fat, hyperandrogenism, insulin resistance, lipid profiles, menstrual cyclicity, fertility, and risk factors for diabetes type 2 and cardiovascular disease in overweight PCOS women.[80]

NON-PHARMACOLOGICAL TREATMENT FOR PCOS

Given that adolescents with PCOS have a metabolic profile that can only moderately be controlled by medication, behavioral interventions focusing on improving physical and emotional disturbances are warranted.[81] Cognitive and behavioral interventions aim to improve sustainability of lifestyle changes by addressing specific behaviors, antecedents, consequences, and cognition. Cognitive Behavioral Therapy (CBT) is a psychotherapeutic approach endorsed for its effectiveness in treating depression. It focuses on altering dysfunctional thought patterns contributing to negative mood states and maladaptive behaviors. CBT educates participants about PCOS symptoms, anatomy, physiology, and endocrinology, promoting positive lifestyle changes, relaxation techniques, and coping skills.[82] Positive affirmations, lifestyle modifications, and daily reflection help reframe negative thoughts and promote emotional regulation.[83] Homework

assignments track progress and reinforce learned practices between sessions, ultimately enhancing Quality of Life in PCOS patients.[84,85]

GOALS OF THERAPY

The primary goal of Cognitive Behavioral Therapy (CBT), recommended by the American Psychological Association and the American College of Physicians for depression treatment, is to modify dysfunctional thought patterns contributing to negative mood states and maladaptive behaviors.[86] This therapeutic approach emphasizes educating participants about their symptoms, course, and prognosis, including reproductive system anatomy and physiology.[87] It also addresses the link between breathing and ovarian health, along with endocrinology underlying the sleep-wake cycle and its relevance to PCOS. The core of CBT involves identifying distressing situations, associated behaviors, and emotions, followed by modifying them using techniques such as restructuring automatic thoughts and regulating emotions to correct cognitive distortions related to physiological arousal.

CBT incorporates positive affirmations and lifestyle modifications, focusing on promoting healthy dietary choices, increased physical activity, and reduced sedentary behavior. Relaxation techniques are practiced to enhance coping skills, followed by engaging in behaviourally activating events within the constraints of daily life. Emphasis is placed on stimulus control and maintaining a consistent sleep schedule, including keeping sleep diaries and practicing sleep restriction. Encouraging positive self-expression and reframing negative thoughts through daily reflection and questioning are essential components of CBT. Homework assignments and worksheets are utilized to track progress and reinforce learned practices between sessions. Additionally, CBT aims to improve Quality of Life in PCOS patients by addressing negative thought patterns, fostering emotional regulation, and promoting good sleep hygiene.

AIMS AND OBJECTIVES

1.) To study the pre and post effect of CBT on Psychological Morbidity in women with PCOS.

2.) To study the pre and post effect of CBT on Quality of Life in women with PCOS.

3.) To study the pre and post effect of Sleep disturbances in women with PCOS.

REVIEW OF LITERATURE

Polycystic ovary syndrome (PCOS) is s a multifaceted hormonal disorder that impacts women's reproductive, metabolic, and psychological well-being. Clinic-based studies indicate that infertility, metabolic, cosmetic problems, mood disturbances including symptoms of depression, decreased sexual satisfaction [53], and problems with feminine identity [42] and decreased QoL are more prevalent in women with PCOS. Three international bodies are have established criteria for diagnosis of PCOS: National Institutes of Health/National Institute of Child Health and Human Disease, [10] "European Society for Human Reproduction and Embryology/American Society for Reproductive Medicine" or the "Rotterdam Criteria;" and the Androgen Excess and PCOS Society.[9] The Rotterdam criteria have been widely accepted for the diagnosis and for reference guidelines across the world and in this study, and is used for patient's selection in several research studies. According to these criteria, presence of any two among oligo/anovulation, hyperandrogenism, and polycystic ovaries on ultrasound is crucial for the diagnosis of Poly cystic ovarian disease (PCOS).

PSYCHOLOGICAL MORBIDITY

Jones & White (2024) [88] performed a study on "Polycystic ovary syndrome and psychiatric morbidity" where the results of the research study indicated that imbalances in Monoamine may contribute in the etiology of psychiatric illness and PCOS. The psychological reaction to acne was found to be clearly significant and psychological problems caused by hirsutism, obesity or menstrual disturbance, were found to be interconnected resulting in psychiatric issues. Significant difficulties in forming interpersonal relationships, and diagnosis of personality disorder and anxiety disorder was made evident in those diagnosed with PCOS. Furthermore, associations between PCOS and conditions

such as manic depressive illness, schizophrenia, and Briquet's syndrome was found to be linked.

A research study was done by Chaudhari. A, et al., (2018) [89] for determination of PCOS symptoms which were further linked to psychiatric morbidity. Patients experiencing psychiatric morbidity exhibited notably lower levels of QoL across three key domains namely, physical and psychological health, along with social and personal relationships. Additionally, individuals with hirsutism demonstrated significantly reduced scores specifically in the domain of psychological quality of life. Moreover, infertility and alopecia were linked with anxiety, whereas acne was linked with depression.

Dokras and cooney, (2017) [48] conducted a research on "Depression and Anxiety in Polycystic Ovary Syndrome: Etiology and Treatment". The study findings reveal that women diagnosed with PCOS have a higher likelihood of experiencing depressive symptoms, which may be partly attributed to factors such as obesity, insulin resistance, and elevated androgens along with anxiety symptoms.

Zehravi et al., (2021) [90] conducted a study titled "Depression and anxiety in women with polycystic ovarian syndrome: a literature survey". The findings suggested that psychiatric morbidities is linked to symptoms like hirsutism, body image issues and obesity in those diagnosed with PCOS as compared to healthy controls.

Yasmin. F. & Asdaq. S. (2020) [91] conducted a study to investigate the frequency of depression, anxiety, and stress among those women diagnosed with PCOS in comparison with those without the condition. Scales pertaining to measure stress as well as anxiety were used to measure the presence of psychological burden. The findings revealed that in comparison with control group PCOS cases had more depression and anxiety symptoms along with stress reported subjectively.

Barth et al. (1993) [92] conducted a study on Psychological morbidity in women referred for treatment of hirsutism. Sixty-nine pre-menopausal hirsute women participated in the study. General Health Questionnaire (GHQ-28), Profile of Mood States (POMS), Eysenck Personality Questionnaire (EPQ-R) and Rosenberg's Self-Esteem Inventory were administered. The results indicated that hirsutism was found to be positively correlated with levels of psychiatric disturbance. It further suggested that greater levels of neuroticism and introversion was found and were significantly correlated with avoidance of social situations.

Lobo and Carmina (1999) [93] did a research study titled "Polycystic Ovary Syndrome: Arguably the Most Common Endocrinopathy Is Associated with Significant Morbidity in Women". The study identified PCOS as a common disorder of women associated with significant reproductive and non -reproductive morbidity. The findings of the study suggests significant correlation of a greater prevalence of reactive depression and minor psychological abnormalities with hirsutism.

Almis et al. (2021) [94] conducted a study titled "Self-Concept, Depression, and Anxiety Levels of Adolescents with Polycystic Ovary Syndrome" to investigate the concerns related to above symptoms along with its severity in adolescents who are diagnosed with PCOS. 53 patients diagnosed with PCOS and 161 adolescents who were identified as healthy participated in the study. The study results showed that adolescents with PCOS had lower self-concept scores, higher levels of anxiety, and increased depressive symptoms when compared to the healthy control group.

Kausar et al., (2022) [95] conducted a study on "Increased Risk of Infertility, Marital Maladjustment and Psychological Morbidity in PCOS Patients of Southern Punjab, Pakistan". 354 women participated in the research study. The findings suggested that the anxiety, depression, sleep apnea, eating disorders, marital maladjustment, poor QoL and migraine was significantly more in women with PCOS as compared to

controls. A significant correlation between infertility and psychotic symptoms; comorbidity between psychological morbidity and infertility was established in PCOS female.

QUALITY OF LIFE

Tabassum et al., (2021) [96] aimed to study the "impact of polycystic ovary syndrome on quality of life of women in correlation to age, basal metabolic index, education and marriage" on women aged between 10–49 years categorized into those undergoing menarche to menopausal period. The findings indicated that higher BMI, irregular menstrual cycles, educational level, and marital status significantly influenced the alteration of Health-Related Quality of Life (HRQOL) in females diagnosed with PCOS.

Karjula (2021) [13] conducted a study on "Long-term consequences of polycystic ovary syndrome on mental health and health related quality of life". The sample comprised of 5889 females. The results suggests that PCOS is rendered as a separate risk factor for psychological distress up to a late reproductive age. An increased risk for psychosis and long-term decrease in HRQoL was found in women with PCOS.

Urgulru and Kokack (2022) [17] did a study to investigate the depressive symptoms and QoL in women with PCOS. 131 women participated in the study. Beck Depression Inventory (BDI) and PCOS Quality of Life Questionnaire (PCOSQ-50) were administered. The study revealed that perceiving income as sufficient and being employed were associated with lower levels of depression, but these variables were positively associated with hirsutism and acne. Quality of life was found to be prevalent among women without depression symptoms compared to those experiencing depression.

A research study was conducted by Burke et al., (2007) [97] as done on 433 patients aged between 15-65 years. The findings revealed

diminished Quality of Life (QoL) and a higher occurrence of issues identified as psychological in those diagnosed with PCOS in comparison to normal population. There was a notable correlation between the mental aspect of QoL and individuals' subjective evaluations of the quality of health-related information, hirsutism as well as menstrual irregularity as established.

Dey in 2018 [98] conducted a study on “Quality of life of women with polycystic ovarian syndrome”. 84 patients participated in the research study. It was noted that patients with PCOS experience a significant reduction in quality of life, which does not seem to be related to the duration of their illness.

“Quality of life in women with polycystic ovarian syndrome: requisite of clinical pharmacist intervention” was studied by et al in Stephans, 2023.[99] The mean age of the subjects was 24 years. Decreased QOL was reflected in the results of women affected with PCOS when compared to controls, wherein the most affected domain was psychological domain. Improvement in QOL was indicated post participation in awareness program imparted in the study.

Thatcher et al., (2018) [100] conducted a study on “Health-Related Quality of Life Issues in Women With Polycystic Ovary Syndrome”. The study aimed to examine how obesity, fertility status, and androgen levels impact the QoL related to health in women with PCOS. PCOSQ (Cronin et al., 1998) was administered to 128 women diagnosed with PCOS. The study revealed that weight was the greatest and body hair was the least reported concern as compared to menstrual disturbance, infertility and emotional difficulties.

Stadnicka. G., et al., (2017) [101] aimed to investigate the correlation between the QoL and the sexuality of females with PCOS. 72 women participated in the study. The findings further indicated significant correlation between the overall QoL and the domains of the sexual

response cycle including desire, lubrication, arousal, orgasm, foreplay and the relations with a partner. The correlation between the QoL in the somatic domain and the majority of women's sexual response cycle domains was found to be statistically significant. Negative correlations were observed in the domain of pain and relations with one's partner where worse quality of life was associated to a more frequent occurrence of pain to a minor extent and to the worse relations with one's partner to a moderate extent.

Devanji.J et al., in 2023 [102] conducted a study on "Improvement In Health-Related Quality of Life in Polycystic Ovarian Syndrome: A Randomized Controlled Trial" aimed for the development of management strategy to improve HRQoL. 114 women participated in the study. Interventions of 12 weeks was designed which included exercises, Rajyoga meditation and diet counselling. The study showed that combination of exercise with diet counselling and Rajyoga meditation led to greater improvements in all domains of PCOS-Q (except for body hair) compared to just diet counselling and Rajyoga meditation. Statistically significant findings were recorded with improved results in all domains of PCOS-Q in both the groups.

A study was conducted by Shilpa. S and Nithya. R (2020) [103] to examine the efficacy of Benson Relaxation and Supportive therapy on QoL and perceived loneliness among PCOS women. A total of 30 women aged between 25-45 years were identified through hospitals in Kerala. Perceived Loneliness Scale and QoL (SF-36) were used. Result of the study revealed that the Supportive and Relaxation therapy were found to be effective in alleviating Perceived loneliness and enhancing QoL among PCOS women.

Sharma (2021) [104] conducted a study on "Relationship between anxiety, depression and quality of life in medical student with polycystic ovary syndrome". 70 medical students from Udaipur, Rajasthan were among the participants in the study. Results revealed that the

participants with PCOS had a deceased QoL scores in comparison to their counterparts.

SLEEP DISTURBANCES

Sleep disruptions encompass various changes in sleep patterns, including alterations in duration, trouble staying asleep, or waking up prematurely or difficulty falling asleep. Insomnia, refers to difficulties initiating or maintaining sleep, often involving prolonged periods of wakefulness during the night while chronic insomnia disorder is diagnosed when such symptoms persist on at least three nights per week for a duration of three months or more. Obstructive sleep apnea (OSA) is characterized by frequent pauses in breathing during sleep and can co-occur with other sleep disturbances. These disruptions in sleep have significant implications for daytime mood, cognitive function, and physical coordination, which can impact overall well-being and daily functioning. Given that PCOS involves metabolic irregularities and the endocrine system plays a significant role in regulating the sleep-wake cycle, it is plausible that PCOS influences arousal and sleep patterns, suggesting a complex interplay between the condition and sleep disturbances.

Naqvi. S. et al., (2014 [105] conducted a study in a clinical sample of women with PCOS. 114 women participated in the research aimed to identify the Predictors of depression in females diagnosed with PCOS. The results revealed that those with a history of depression had a threefold increase in disturbed sleep highlighting its link with genetics.
Hung et al. (2014) [106] conducted a study aimed at diagnosing new onset sleep disorders. 5431 with PCOS and 21,724 without PCOS women participated in the research study. The results showed that individuals with PCOS had a higher likelihood of being diagnosed with sleep disorders.

Moran et al., (2015) [107] conducted a study aimed at evaluating the temporal association between PCOS and Obstructive sleep apnea. The results indicated that the women diagnosed with PCOS were linked with a greater risk of developing OSA in later life. Sleep disturbances were found to be two times higher in women with PCOS in comparison with the control. It has been proposed that poor sleep is integrated into the pathophysiology of PCOS, which is seen as a condition involving significant metabolic strain, leading to subsequent oxidative and psychological stress.

A study was conducted by Hachul. H., et al., (2018) [108] aimed at evaluating the sleeping pattern of those diagnosed with PCOS, with and without hyperandrogenism in comparison to healthy control group and to examine if the hyperandrogenism and obesity has any effect on sleeping parameters. 44 females participated in the study. The study revealed that women with PCOS presented poorer subjective sleep quality with there is a greater prevalence of snoring and an elevated likelihood of experiencing obstructive sleep apnea as indicated by reduction in REM stage. The findings indicated no significant difference in sleeping parameters of PCOS women versus those without hyperandrogenism.

COGNITIVE BEHAVIOR THERAPY

CBT, recommended by the American Psychological Association and the American College of Physicians as a first-line treatment for depression (Qaseem, 2016) [87], is a psychotherapy that focuses on changing dysfunctional thoughts that lead to negative mood states and maladaptive behaviors (Gelenberg et al. 2010).[109] It has been posited that cognitive-behavioural therapy (CBT) in combination with practical medical science techniques can assist women diagnosed with PCOS in overcoming barriers to coping with lifestyle changes and in recovering from the progression of their disease.[110] Previous research in cognitive behavioural therapy has suggested that insomnia often arises

and persists due to dysfunctional beliefs about sleep, spending excessive time in bed, inappropriate sleep scheduling, and poor sleep hygiene. Cognitive behavioural therapy for insomnia aims to improve sleep disturbances by replacing these dysfunctional beliefs and attitudes with more adaptive and functional concepts. Evidence suggests that CBT resulted in improvement in depression in adolescents with PCOS. Meta-analytic studies has posited that CBT showed moderate to large treatment effects for GAD and major depressive disorder.[111] CBT has rather not been studied much in adult women with PCOS to assess its effectiveness in reducing depressive and anxiety symptoms. Despite growing interest and research, it remains uncertain how the psychological and psychiatric well-being, as well as HRQoL of females with PCOS are influenced as they age leading up to menopause. There is a paucity of literature in Indian continent addressing the effects of CBT on relationship between Psychological morbidity, Quality of life and sleep disturbances in women with PCOS. Therefore, overall aim of the study is to compare the feasibility and preliminary efficacy of an intervention which combined CBT and pharmacological treatment versus pharmacological treatment alone in the concurrent treatment of aforementioned variables in women with PCOS. Thus, this study aims to study the above aspects namely relationship between Psychological morbidity, quality of life, psychological fatigue and sleep disturbance in women with PCOS in India.

Rofey et al. (2008) [112] conducted a study on “Cognitive Behavioural Therapy for Physical and Emotional Disturbances in Adolescents with Polycystic Ovary Syndrome: A Pilot Study”. A total of 12 adolescents with PCOS, obesity, and depression underwent an open trial where weekly sessions (8) family-based sessions of CBT (3) enhanced by lifestyle goals, physical illness narrative and family psychoeducation was provided. Results of the study indicated significant reduction in weight across and the depressive symptoms the eight sessions. A manual-based CBT approach was used to treat depression in

participants who were adolescents who have been diagnosed with PCOS where obesity was indicated to be promising as indicated by the results of the study.

Tang et al., (2022) [113] conducted a meta-analytical study to evaluate the effectiveness of CBT in improving weight loss, anxiety, depression, life quality, compliance, and pregnancy outcomes in patients with PCOS. Results revealed that CBT resulted in the reduction of anxiety, improvement of QoL in hirsutism, increased compliance and rate of pregnancy in patients with PCOS.

M. Pilar Martínez et al. (2013) [114] conducted a study to examine “the efficacy of a cognitive-behavioural therapy for insomnia (CBT-I) versus a sleep hygiene (SH) education program at improving sleep and other clinical manifestations in fibromyalgia”. A total of 59 fibromyalgia women with insomnia participated in the study. The findings revealed significant improvement was reported by the group receiving CBT for Insomnia in variables of sleep, fatigability, daily functioning, pain catastrophizing, anxiety and depression Significant improvement in subjective sleep quality was reported by the Sleep hygiene group. The findings further emphasized the efficacy of CBT- Insomnia in the management of fibromyalgia with a multidisciplinary approach.

Espie et al., (2018) [115] conducted a study on “Effect of Digital Cognitive Behavioural Therapy for Insomnia on Health, Psychological Well-being, and Sleep-Related Quality of Life: A Randomized Clinical Trial” to determine the effect of digital CBT for insomnia, sleep-related quality of life and psychological well-being in order to assess whether alleviation in insomnia symptoms was a mediating factor. A total of 1711 participants with self-reported symptoms of insomnia participated in the study. Digital Cognitive behavior therapy and sleep hygiene education were provided for 12 weeks. The findings indicated that the use of digital CBT was effective in improving psychological well-being, functional health, and sleep-related QoL in people reporting insomnia

symptoms. An alleviation in insomnia symptoms was found to mediate those improvements. The study highlighted that digital CBT improves both daytime and night time aspects of sleep disturbances like insomnia, further elaborating on existing recommendations of CBT as the treatment intervention of choice for insomnia.

Babapaur et al., (2018) [116] conducted a study to "determine the effects of cognitive-behavioral therapy (CBT) on the quality of life and psychological fatigue in women with the PCOS". 74 females aged between 18 and 35 years from Iran participated in the study. The results showed that CBT contributed in reduction of fatigue and improved QoL in women with the PCOS.

Cooney et al., (2018) [117] conducted a study to examine "Cognitive-behavioural therapy improves weight loss and quality of life in women with polycystic ovary syndrome: a pilot randomized clinical trial". A total of 7 women participated in the study. Weekly intervention of CBT along with contact only/no intervention was provided for 8 weeks to experimental and control group respectively where both the groups received weekly Life style intervention for 16 weeks. Results of the study showed that the combination of weekly CBT and lifestyle modification (LS) for 8 weeks resulted in significant weight loss and improved quality of life in obese women with PCOS and depressive symptoms as compared to with Life style modification alone. The study results suggest a possible connection between Cognitive Behavioral Therapy (CBT), weight reduction, and regulation of the stress response among women diagnosed with PCOS.

MATERIALS AND METHODS

SOURCE OF DATA

Study will be conducted on 30 patients diagnosed with PCOS by the gynaecologist, admitted in Gynaecology ward or visiting gynaecology OPD at Dayanand Medical College and Hospital, Ludhiana.

SAMPLE COLLECTION

The study included 30 female patients diagnosed with PCOS by the gynaecologist visiting gynaecology OPD at Dayanand Medical College and Hospital, Ludhiana within the age range of 18-35 years.

RESEARCH DESIGN

Pre- and post-design was used for the current study. Participants underwent a pre-test, then received treatment intervention, followed by post-test administered in the end of the intervention. Post which, follow up was taken after 2 months.

SAMPLING TYPE

Purposive sampling design was used to form sample for data collection. Sample size estimation was used to ascertain the number of participants required for the study. Purposive sampling involved deliberately selecting specific participants who met the inclusion criteria relevant to the research questions.

INCLUSION CRITERIA

- Fulfilment of Rotterdam's criteria (2003): 2 out of 3 diagnostic criteria of oligo/anovulation, clinical or biochemical hyperandrogenism, and a diagnosis of polycystic ovaries based on ultrasound results (on treatment).[9]
- Female participants belonging to an age group between 18 to 35 years willing to give informed consent.

EXCLUSION CRITERIA

- Presence of Hypothyroidism (untreated).
- Presence of Hyperprolactinemia (untreated).
- Pregnant females.
- Presence of any other medical comorbidity were excluded.
- History of substance use disorder.
- Language or cognitive problems preventing reliable completion of the questionnaire.
- History of Intellectual disability.
- Presence of any major psychiatric illness.

DESCRIPTION OF THE TOOLS:

i. **Socio- demographic Proforma (Kuppuswamy, 2023)** [118]: **Informed consent form.**

A semi structured pro-forma was designed for the present study in order to collect detailed clinical history of each participant including information related to the following areas:

• Socio-demographic details including age, gender, MRD number, occupation, education, income, time since diagnosis and pharmacological intervention.

ii. **Hamilton depression rating scale (HDRS):** [119] This is a multiple item questionnaire used to rate the severity of depressive symptoms. Eight items are rated on a 5-point scale (0=absent; 1=doubtful or mild; 2=mild to moderate; 3=moderate to severe; 4=very severe), while the remaining 9 items are rated on a 3-point scale (0=absent; 1=doubtful or mild; 2=clearly present). The theoretical score range of the scale is from 0 to 52. A score of 0–7 is generally accepted to be within the normal range (or the patient is in the clinical remission phase), 8-16 indicates mild depression, 17-23 indicates moderate depression, 24 or higher indicating at severe depression. (Hamilton, 1967)

[119]. Internal consistency of the test was found to be >80. (Dedeken.P et al., 2020).[120]

iii. **Hamilton anxiety rating scale (HARS)**[121]: The scale consists of 14 items, each defined by a series of symptoms, and measures both psychic anxiety (mental agitation and psychological distress) and somatic anxiety. The score of each item is done on a likert scale of 0 (not present) to 4 (severe), with a total range of 0–56, where <17 suggest mild severity, 18–24 mild to moderate severity and 25–30 moderate to severe. (Hamilton, 1959). Internal consistency of the test was found to be 0.77 to 0.92. (Hamilton. M, 1959).[121]

iv. **Polycystic Ovary Syndrome Questionnaire (PCOSQ)**: This 26-item questionnaire, developed by Cronin et al,1998 [122] measures quality of life among respondents in the following domains: emotional (items 2, 4, 6, 11, 14, 17, 18 and 20), hirsutism / body image (items 1, 9, 15, 16 and 26), weight (items 3, 10, 12, 22 and 24), infertility (items 5, 13, 23 and 25), and irregular menstruation (items 7, 8, 9 and 21). Each item is given a score according to a seven-point Likert scale, with a score of 7 showing the best performance and a score of 1 showing the weakest performance. Thus, the range of score for the emotional domain is between 8 and 56 points, for the hirsutism and weight domains between 5 and 35 points, and for the infertility and menstrual domains between 4 and 28 points. The total score in each domain is the score of that domain divided by the total of all the items in that domain. Higher scores indicate better function. Cronbach's α fluctuated between 0.70 and 0.85. (Lim, 2022).[123]

v. **Pittsburgh Sleep Quality Index (PSQI)**: The Pittsburgh Sleep Quality Index (PSQI) was developed by Buysse, Reynolds, Monk, Berman, & Kupfer in 1989.[124] This measure consists of

19 items grouped into seven components, each scored on a scale of 0 to 3. A score of 0 indicates no difficulty, while a score of 3 indicates severe difficulty. The seven components assess various aspects of sleep quality over the past month, including sleep duration, disturbance, latency, daytime dysfunction, efficiency, quality, and medication use. The initial four items require open-ended responses about typical sleep and wake times, as well as sleep latency and duration. The remaining 14 items ask participants to rate the frequency of different sleep disturbances, such as waking up during the night or experiencing daytime sleepiness, on a four-point scale. Component scores are calculated by summing the scores of relevant items, resulting in a global sleep quality score ranging from 0 to 21. Higher scores indicate greater sleep disturbance, with scores of 5 or higher typically indicative of a clinical sleep problem. A score of 5 or less suggests good sleep quality, while scores above 5 indicate poor sleep quality.

PROCEDURE

Baseline assessment- The informed consent of the patients were taken, in which the necessary information was provided to enable the participants to make an informed decision. The participants who were meeting the inclusion criteria and those willing to give consent were then included in the study. The Socio demographic proforma (Kuppuswamy, 2023) [118] containing the basic information about the patient was filled.

Further, the participants were assessed on Hamilton depression rating scale (HDRS), Hamilton anxiety rating scale (HARS), Polycystic Ovarian Syndrome- Quality of Life scale (PCOS-QoL) and Pittsburgh Sleep Quality Index (PSQI) in baseline assessment prior to intervention.

After the assessment, each participant had undergone 12 weekly sessions of CBT of 70 minutes (40 minutes CBT+ Relaxation) each. Patients were re-evaluated on baseline assessment post intervention and follow up was taken after 2 months. Scores were compared and analysed using appropriate statistical analysis.

Table A. session plan (adapted by Rofey, 2000 and Abdollahi, 2019)[54]

S.NO	SESSION	AREA
1	Baseline appointment	Reviewing history, Baseline assessments
2	Session 1	Explaining the anatomy and physiology of the reproductive system, defining the ovaries and the mechanism of their function. Information about the relationship between sleep and PCOS, basic notions about sleep, and sleep hygiene education. Introduction and maintenance of sleep diary along with Thought diary. Diaphragmatic breathing.
3	Session 2	Follow up on the previous session's assignment in consecutive sessions. ABC Model; Identifying situations, behaviors, emotions that leads to distress. Maintenance of thought diary. Practice of relaxation techniques.
4	Session 3	Follow up on the previous session's assignment in consecutive sessions. Identification of Cognitive distortion. Self affirmative statements were

		introduced. Maintenance of thought diary. Sleep hygiene would be emphasized along with Jacobson Progressive Muscle Relaxation (JPMR).
5	Session 4	Information about the role of Lifestyle modification in PCOS was introduced. Behavioral activation. Maintenance of thought diary.
6	Session 5	Follow up on the previous session's assignment in consecutive sessions. Modifying negative cognitive distortions and attributions concerning health aspects, emotions, and physical self. Identification of negative self talk along with generation of empowering alternatives. Jacobson Progressive Muscle Relaxation (JPMR).
7	Session 6	Follow up on the previous session's assignment in consecutive sessions. Changing negative automatic thoughts about sleep disturbance. Behavioral experiments was focused upon. Reassessment of lifestyle goals. Jacobson Progressive Muscle Relaxation (JPMR).
8	Session 7	Problem solving: Pros & Cons of behavior. Stimulus control and Sleep restriction was introduced.

		Practice of relaxation techniques.
9	Session 8	Follow up on the previous session's assignment in consecutive sessions. Increment in physical exertion. Problem solving: Identification of the problem, Generation of potential solution, Evaluation of alternatives. Practice of relaxation techniques.
10	Session 9	Follow up on the previous session's assignment in consecutive sessions. Problem solving: Implementation of the solution, evaluating outcome. Practice of relaxation techniques.
11	Session 10	Follow up on the previous session's assignment in consecutive sessions. Review Behavioral experiment and discuss the barriers experienced. Self- management. Building autonomy. Practice of relaxation techniques.
12.	Session 11	Maintenance of achievements and prevention of relapses. Practice of relaxation techniques.
13.	Session 12	Follow up and therapy termination. Post intervention assessment
14.	Follow up	

Pre- test phase: Introductory session:

• Objectives of the study were explained to the participants.

• Informed consent was taken.

• Participant were informed regarding the voluntary type of the study & the right that they can even withdraw their participation from the study at any given point of time. They were told about the future implications of the study and their right to ask for results of the study if they wished to. All the participants were beforehand notified regarding the active nature of the intervention to be used in the study.

• Building rapport with the participants was focused upon.

• Socio demographic Proforma was filled.

• Detailed case history of the patients was taken.

. • Later on, they were evaluated for anxiety, depression, quality of life and sleep disturbances using the infamous depression rating scale of Hamilton (HDRS), Hamilton anxiety rating scale (HARS), Polycystic Ovarian Syndrome - Quality Life scale (PCOS-QoL) and Pittsburgh Sleep Quality Index (PSQI).

Session 1

Information about the anatomy and physiology of the reproductive system, mechanism of the ovaries, link of pathophysiology of PCOS to sleep disturbances was highlighted by sharing of information about the relationship between sleep and PCOS where basic notions about sleep were discussed. Difficulties with sleep and sleep hygiene, goals for changing sleep habits were elaborated upon. Participants were given sleep diaries along with sleep hygiene checklist and were taught as to how to use them. The sleep diary acted as a behavioural monitoring device for the individuals, as daily recordings of the sleep variables obliged the participants to be more aware of their sleep habits on a daily basis. During the sessions, the investigator examined the sleep diary in detail with the participant and elaborated upon the following therapeutic techniques of maintaining sleep hygiene by maintenance of sleep timing regularity, avoidance of daytime napping and avoidance of bedtime technology use along with management of stress using relaxation exercises. Maintenance of thought diary was emphasized.

Between session assignment: Diaphragmatic breathing was introduced.

Session 2

The patient's comprehension of the previous session was assessed during a 5-minute bridging session, where the key concepts were reinforced using a bridging worksheet. This reinforcement was deemed crucial for the patient's progress outside of the therapeutic setting. Creating awareness and Identification of how situations influence thoughts and behaviors and emotions was addressed. A seven-column Thought record was provided to challenge unhelpful thoughts and beliefs. The initial part of the session introduced the first three sections of the thought record sheet: situation, automatic thoughts, and emotions/mood. The concept of "hot thoughts" was also discussed, emphasizing their significance in the cognitive restructuring process. Practical application of these concepts was demonstrated by practicing the thought record sheet using a specific event from the previous week. Once a hot thought and its accompanying emotion were identified and rated, the hot thought was questioned to generate evidence for and against it.

Between session assignment: Guided imagery was practised to ease stress and promote an overall sense of well-being, and receiving feedback.

Session 3

The technique of positive self affirmations in order to foster acceptance and rational perspective was emphasized upon. Participants were asked to reflect upon personal core values and rewarding experiences to engage neural mechanisms associated with reward and positive valuation. Identification of negative cognitive distortions and attributions regarding health, emotions, and physical self along with maintenance of sleep hygiene was emphasized. Relaxation exercise was practiced.

Between session assignment: Planning for progressive muscle relaxation twice a day, and receiving feedback. Maintenance of thought diary was emphasized.

Session 4

Participants were encouraged to use exercise as part of their daily routine for 30 mins daily. Making healthy food choices as per the DFG guide along with the intake of healthy, sustainable food choices and avoidance of “restrained” behaviour like skipping meals and reducing food variance was emphasized upon. Structured eating pattern to avoid over-restriction and under-restriction, like binge eating and restrained eating based on the principle of proactive coping was highlighted for lifestyle modification. Behavioural skills developed would be further reinforced. Modification of identified cognitive distortion was done. Behavioral activation including a set of procedures and techniques aimed at increasing patient activity and access to reinforcing situations that improve her mood and functioning was emphasized along with its rationale. Re-introduction of pleasant events using behavioral activation along with reversing avoidance was highlighted. Active coping in order to decrease stress through accomplishment or overcoming avoidance was focused upon. Activation was measured and documented in the form of number, frequency, or duration of activities to track the progress. Jacobsons Progressive muscle relaxation was practiced.

Between session assignment: Jacobsons progressive muscle relaxation twice a day, Behavioural activation followed by receiving feedback. Maintenance of thought diary was emphasized.

Session 5

The last four columns of thought record: Generation of alternative thought using evidence and the believability of alternative thought was rated. Re-rating of emotion of hot thought was elicited by generation of alternative thought. Modification of identified patterns of negative cognitive distortions and targeting the core beliefs regarding health, emotions, and physical self was done. Unhelpful thinking style was identified and challenged using socratic questioning. Socratic questioning involved asking a series of open-ended, brief questions

that guided patients to discover their idiosyncratic thoughts, feelings, or behaviors associated with a particular situation for it to be exposed to the unhelpful thought or belief so that it was challenged. Cognitive restructuring was done to challenge myths or thinking styles which were unhelpful and was associated with fear. Identification of negative self talk and replacing it with generation of positive empowering alternatives was emphasized. Jacobsons Progressive muscle relaxation was practiced.

Between session assignment: Action plan and activity scheduling was done.

Session 6

All the core concepts covered in previous sessions were brushed and summarised for the participants to have a better understanding as to how to implement them together in their lives. Changing negative automatic thoughts about sleep disturbance would be focused upon. Generation of alternative thought for elicited themes and negative automatic thoughts generated in the thought record was done by generating evidences and the believability of alternative thought was rated. Patient was given repeated and graded exposure to situations in which fear or physiological sensations were anticipated. Behavioral experiments were practiced for it to help the patient devise a behavioral test to evaluate the validity of a core belief along with reassessment of lifestyle goals.

Between session assignment: Participants were asked to daily continue with practices taught throughout the sessions. Behavioural experiment were provided in order to ensure generalization of learned concepts to different situations.

Session 7

Problem-solving techniques were introduced which included identification of effective means of coping with problems to enable

patients to perform the strategies after therapy ends. Short as well as long term goals were discussed along with identification of pros and cons of continuing the current behavior was done using decisional balance scale to create insight about the maladaptive behavior. Techniques of Stimulus control and Sleep restriction were highlighted introduced as a part of sleep hygiene. Relaxation exercise was practised.

Between session assignment:
Maintenance of sleep hygiene and thought record.

Session 8

Techniques of problem solving were discussed by identifying problem areas, generation of potential alternative options for coping along with evaluation of the options was discussed. Increment in physical exertion was done by focusing on elimination of sedentary behavior. The barriers in execution of behavioural experiments were targeted and discussed. Relaxation exercise was practised.

Between session assignment:
Completing the seven-column thought record sheet (situation – automatic thoughts - emotions and mood - confirming evidence - rejecting evidence - alternative thinking - re-evaluating) along with brainstorming on problem solving was suggested followed by receiving feedback.

Session 9

Problem solving skills were further discussed by developing strategies for implementing upon the chosen alternative were suggested. Adaptive coping in order to decrease stress through accomplishment or overcoming avoidance was focused upon.

Between session assignment:
Identifying problems and brainstorming upon possible solutions to identified problem. Completing the seven-column thought record sheet (situation – automatic thoughts - emotions and mood - confirming evidence - rejecting evidence - alternative thinking - re-evaluating) and receiving feedback.

Session 10

Reviewing Behavioural activation documented in the form of number, frequency, or duration of activities suggested and activity scheduling to track the progress and adaptability to changing environmental demands. Self- management skills were advised using self-management worksheet which included mood check and problems that can occur before next self-management time. Building autonomy was emphasized by reinforcing the achieved goals and skills. Relaxation was practised.

Between session assignment: Participants were encouraged to evaluate pros and cons in order to elicit any hindrance to desired goals and receiving feedback.

Session 11

Maintenance of achievements and prevention of relapses was ensured using anticipation of potential stressors and symptoms using functional assessment. Barriers for change were highlighted and changes were encouraged accordingly.

Between session assignment:
Monitoring of progress in mood, mastery, and confidence was identified through homework assignments in order to assist the patient to document the frequency and behavioural activity and any other corresponding emotions of mastery or confidence. On the basis of this monitoring of outcomes, evaluation of the action plan and the patient's ability to work towards achieving goals were monitored.

Session 12

The previously learned techniques were reviewed. Post the competition of the 11th session, the observations were revaluated, for anxiety, depression, QoL and sleep disturbances. Any query which they may have been asked during the study were cleared. They were very well notified about their right to obtain the findings of the said study. They were further shown gratefulness for their active participation and sincere disclosure of personal information in the study.

Follow up

Those who participated were revaluated, for anxiety, depression, quality of life and sleep disturbances using appropriate tools. Maintenance of skills learnt were re-emphasized.

OBSERVATIONS AND RESULTS

Table 1. Mean age of participants diagnosed with PCOS.

Age range	Percentage
18-24	40
25-30	33.3
31-35	26.7

Figure 1. Mean age of participants diagnosed with PCOS.

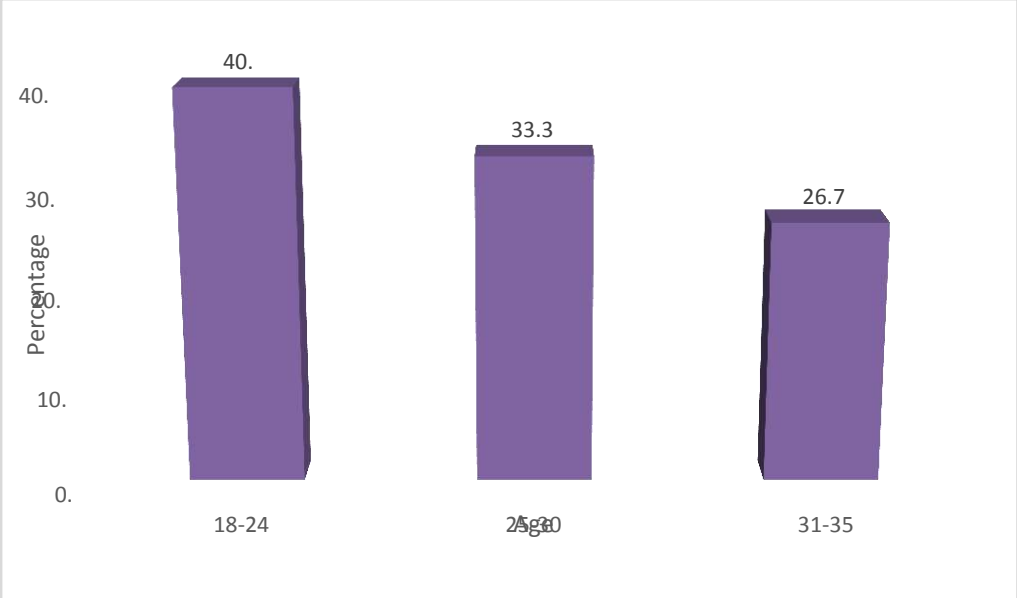

Table 2. Level of educational qualification of participants diagnosed with PCOS.

Education	No. of cases	Percentage
Graduate	1	3.3
Intermediate or diploma	2	6.7
High school certificate	10	33.3
Middle school certificate	10	33.3
Primary school certificate	7	23.3

Figure 2. Level of educational qualification of participants diagnosed with PCOS.

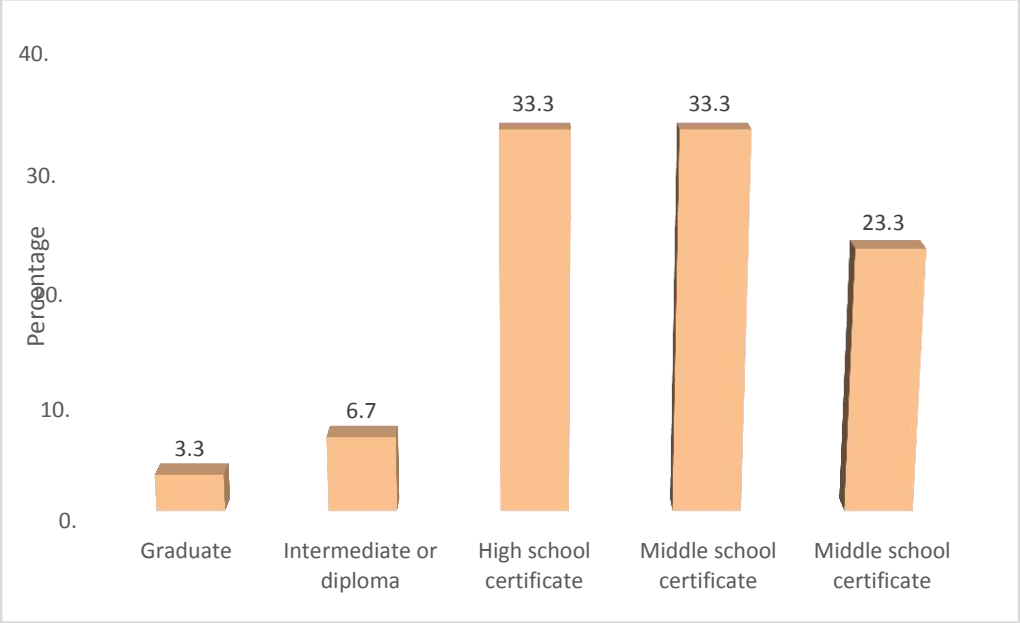

Table 3. Occupational distribution among participants diagnosed with PCOS.

Occupation	No. of cases	Percentage
Semi-skilled/ skilled worker	1	3.3
Unemployed	12	40
Other	2	6.7
Professional	5	16.7
Student	10	33.3

Figure 3. Occupational distribution among participants diagnosed with PCOS.

Table 4 Distribution of family type among participants diagnosed with PCOS

Family type	Frequency	Percentage
Nuclear	23	76.7
Joint	7	23.3

Figure 4 Distribution of family type among participants diagnosed with PCOS

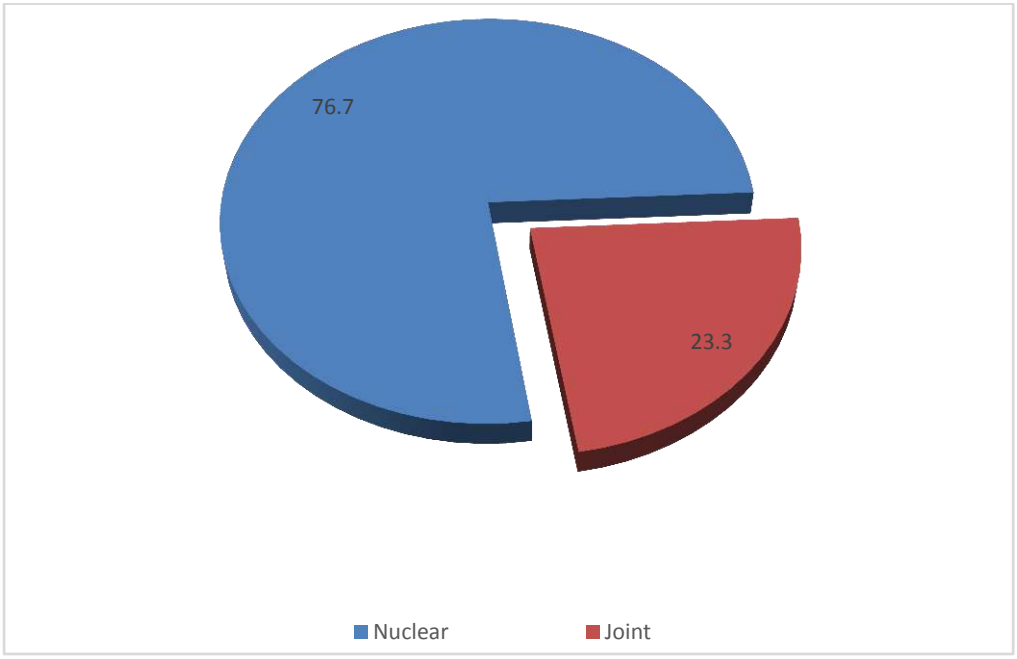

Table 5 Distribution of Occupation of the head of the family among participants diagnosed with PCOS.

Occupation	Percentage
Unemployed	33.3
Elementary occupation	13.3
Plant and machine operator	43.3
Craft and related trade worker	6.7
skilled/ shop/market workers	3.3

Figure 5. Distribution of Occupation of the head of the family among participants diagnosed with PCOS.

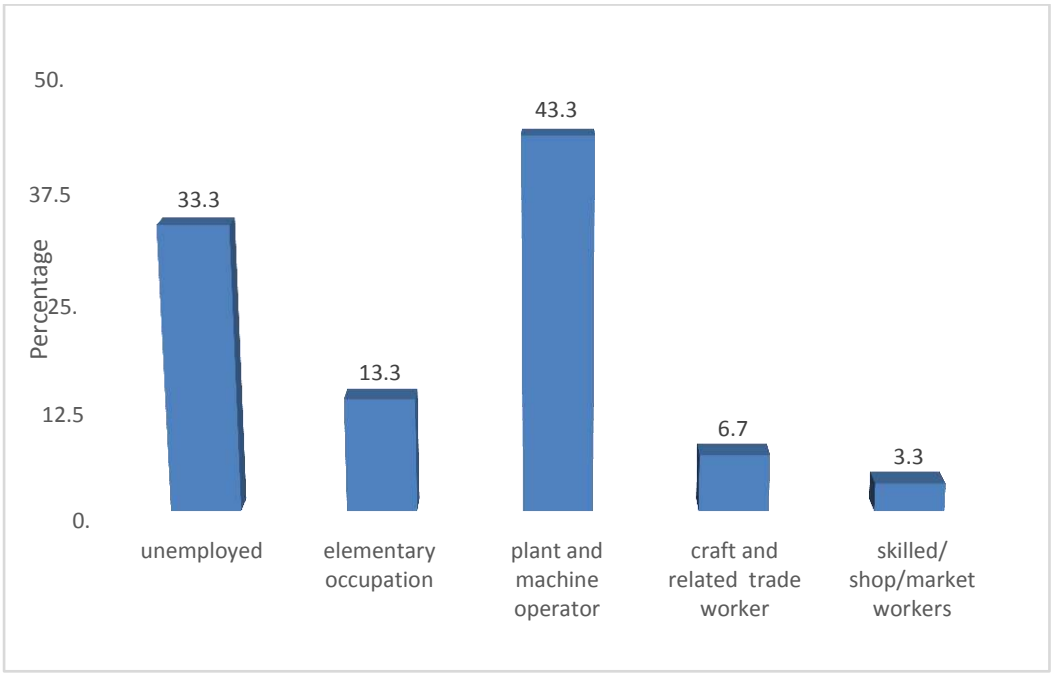

Table 6. Distribution of Education of the head of the family among participants diagnosed with PCOS

Profession or honors	6.7	2
Graduate	33.3	10
Intermediate or diploma	13.3	4
High school certificate	3.3	1
Middle school certificate	20	6
Primary school certificate	16.7	5
Illiterate	3.4	2

Figure 6. Distribution of Education of the head of the family among participants diagnosed with PCOS.

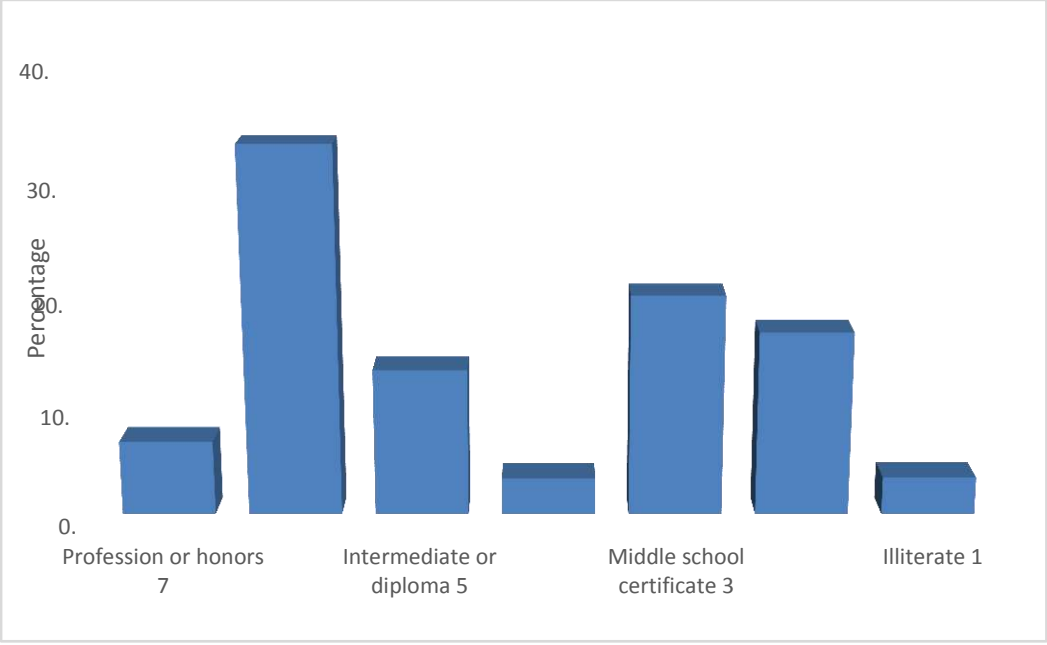

Table 7. Socioeconomic status distribution among participants diagnosed with PCOS.

Socio-economic status	Percentage
Upper class	33.3
Upper middle class	40
Lower middle class	13.3
Upper lower class	13.3

Figure 7. Socioeconomic status distribution among participants diagnosed with PCOS.

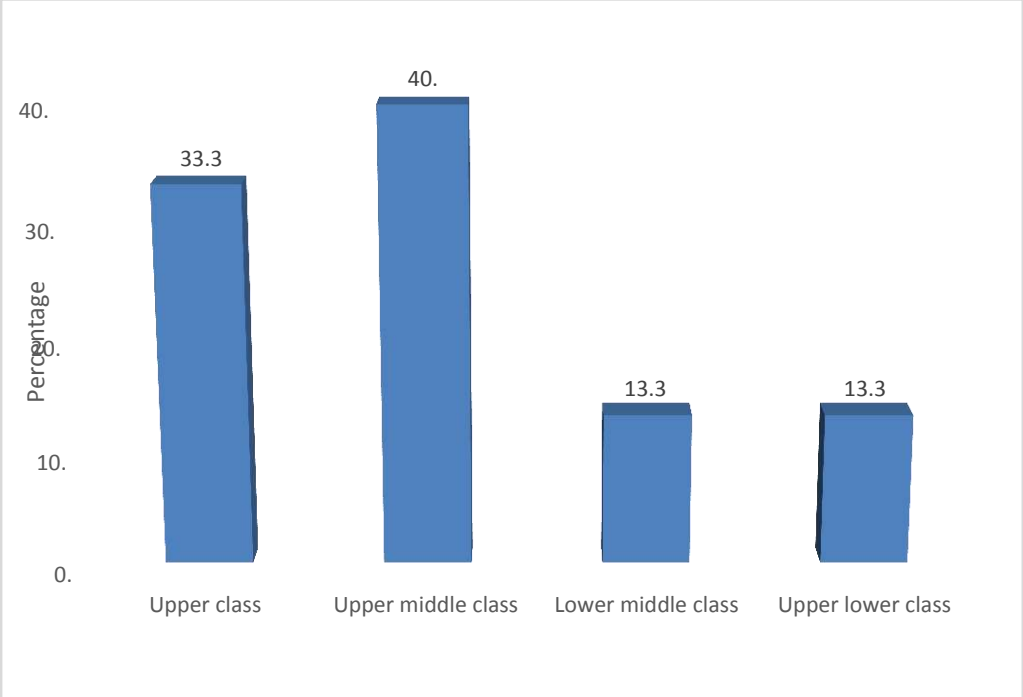

Table 8. Comparison of Pre and Post intervention scores of Depression on HDRS.

	Pre		Post		t	p-value
	Mean	SD	Mean	SD	6.444	<0.001
HRDS	15.80	7.770	7.60	4.538		

Figure 8. Comparison of Pre and Post intervention scores on HDRS.

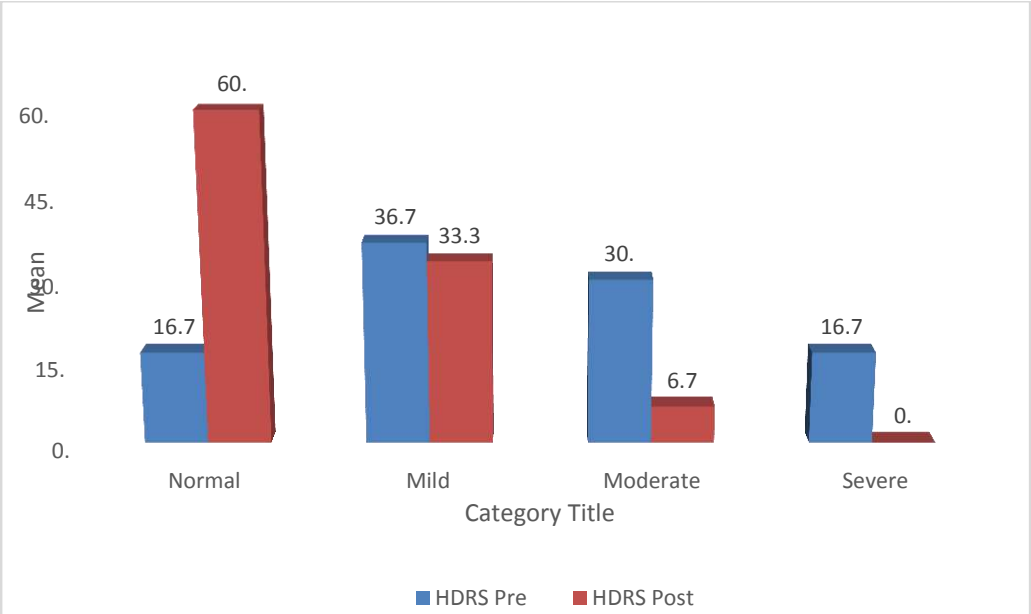

Table 9. Comparison of Post intervention and scores after follow up of Depression on HDRS.

	POST		FU		t	p-value
	Mean	SD	Mean	SD	1.890	.069
HRDS	7.60	4.538	6.23	2.373		

Figure 9. Comparison of Post intervention and scores after follow up of Depression on HDRS.

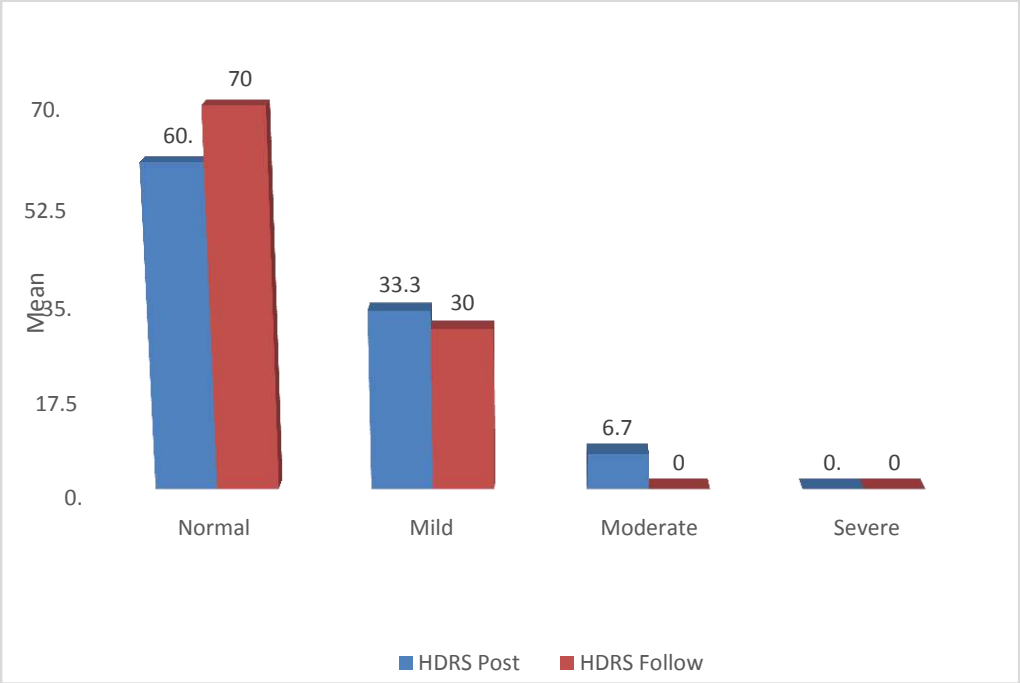

Table 10. Comparison of Pre and Post intervention scores of anxiety on HARS

	Pre		Post		t	p-value
	Mean	SD	Mean	SD	6.247	0.001
HARS	15.97	8.024	7.87	4.783		

Figure 10. Comparison of Pre and Post intervention scores of anxiety on HARS

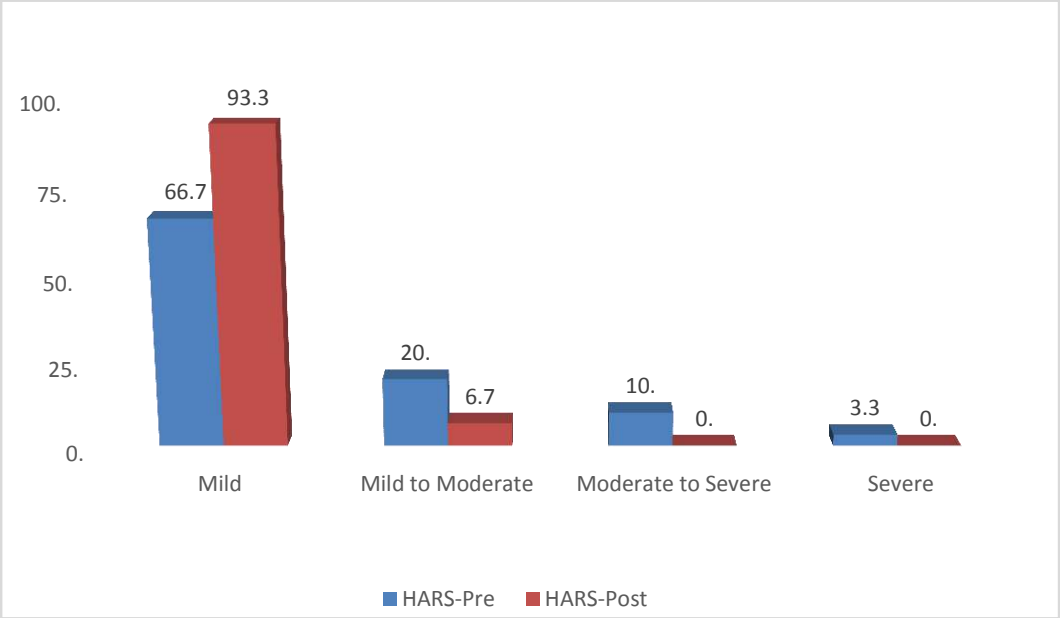

Table 11. Comparison of Post intervention and Follow up scores of anxiety on HARS

	POST		FU		t	p-value
	Mean	SD	Mean	SD	1.747	0.091
HARS	7.87	4.783	6.43	2.800		

Figure 11. Comparison of Post intervention and Follow up scores of anxiety on HARS.

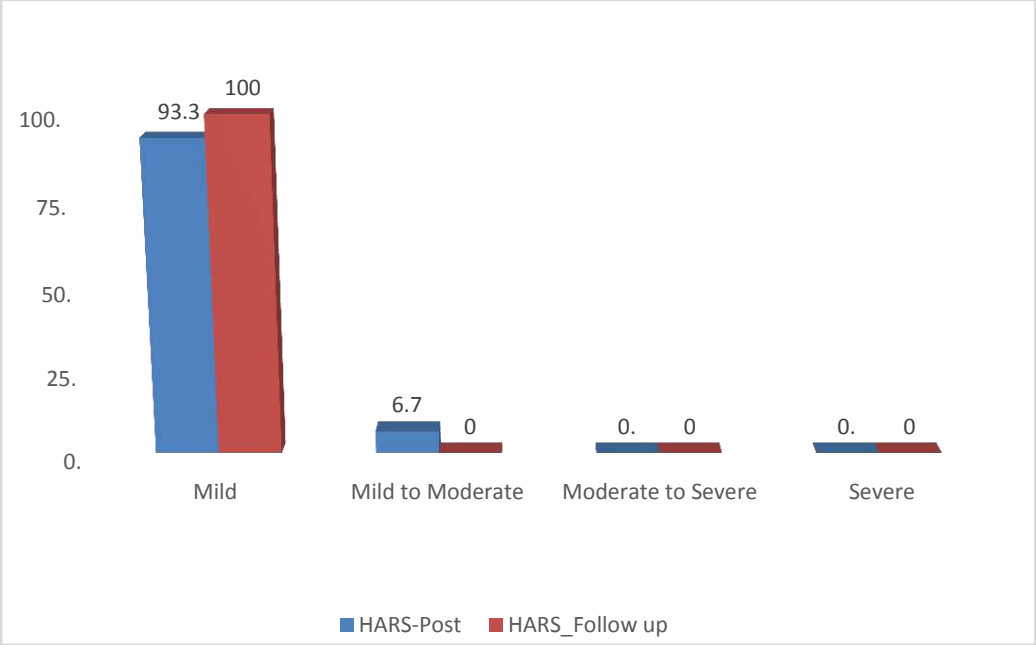

Table 12. Comparison of Pre and Post intervention scores on PSQI.

	Mean	Std. Deviation	z	p-value
PSQI PRE	8.03	4.650	-3.228	.001
PSQI POST	4.50	3.350		

Figure 12. Comparison of Pre and Post intervention scores on PSQI.

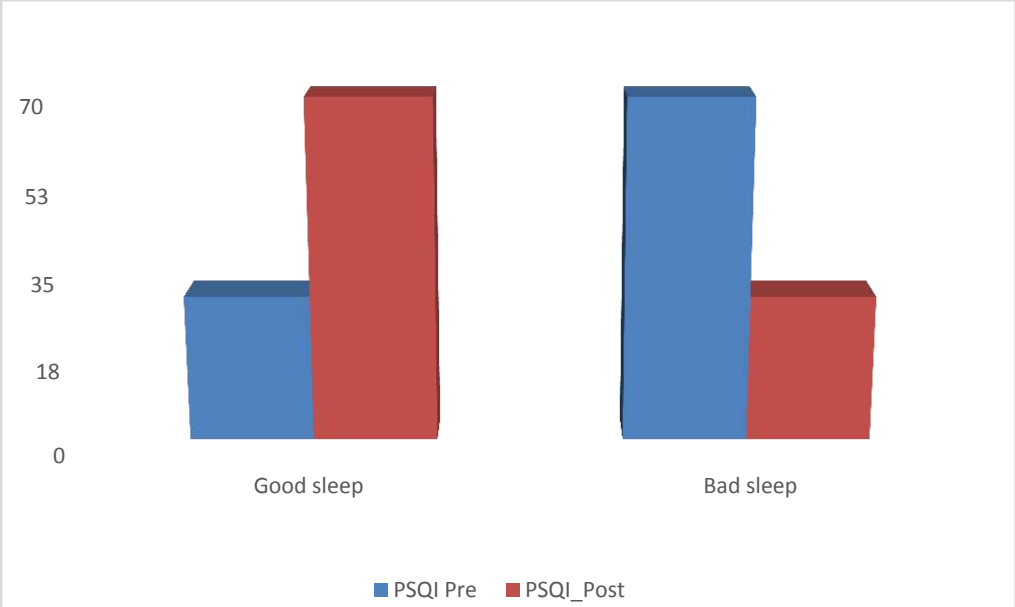

Table 13. Comparison of Post intervention and after follow up scores on PSQI.

	Mean	Std. Deviation	z	p-value
PSQI POST	26.70	3.789	-1.352	.176
PSQI FOLLOW UP	28.57	3.370		

Table 14. Comparison of Pre and Post intervention on Emotional domain on PCOS-QOL scale.

	Mean	Std. Deviation	z	p-value
E-PRE	4.13	1.137	-4.357	<.001
E-POST	5.57	.728		

Table 15 Comparison of Post intervention and after follow up scores on Emotional domain on PCOS-QOL scale.

	Mean	Std. Deviation	z	p-value
E-POST	5.57	.728	-2.355	.019
E-FU	5.97	.718		

Table 16. Comparison of Pre and Post intervention on Body image domain on PCOS-QOL scale.

	Mean	Std. Deviation	Z	p -value
B-PRE	4.40	1.754	-3.559	<.001
B-POST	5.47	1.306		

Table 17. Comparison of Post intervention and after follow up scores on Body image domain on PCOS-QOL scale.

	Median	Z	p -value	r
B-POST	6	2.4	0.017	0.6
B-FU	6			

Table 18. Comparison of Pre and Post intervention on Weight domain on PCOS-QOL scale.

	Mean	Std. Deviation	Z	p -value
W-PRE	3.93	1.874	-3.559	<.001
W-POST	4.93	1.172		

Table 19. Comparison of Post intervention and after follow up scores on Weight domain on PCOS-QOL scale.

	Median	Z	p -value	r
W-POST	5	1.8	0.065	0.4
W-FU	6			

Table 20. Comparison of Pre and Post intervention scores on Infertility domain on PCOS-QOL scale.

	Mean	Std. Deviation	Z	p- value
I-PRE	4.90	1.826	-2.722	.006
I-POST	5.70	1.601		

Table 21. Comparison of Post intervention and after follow up scores on Infertility problem domain on PCOS-QOL scale.

	Median	Z	p -value	r
I-POST	6.5	0.8	0.425	0.2
I-FU	6.5			

Table 22. Comparison of Pre and Post intervention scores on Menstrual problem domain on PCOS-QOL scale.

	Mean	Std. Deviation	Z	p value
M-PRE	3.83	1.206	-4.320	<.001
M-POST	5.03	1.066		

Table 23. Comparison of Post intervention and after follow up scores on Menstrual problem domain on PCOS-QOL scale.

	Median	Z	p -value	r
M-POST	5	0.8	0.425	0.2
M-FU	6			

Table 24. Comparison of Pre and Post intervention scores on PCOS-QOL scale.

	Mean	Std. Deviation	z	p-value
PCOSQOL PRE	21.20	5.851	-4.760	<.001
PCOSQOL POST	26.70	3.789		

Table 25. Comparison of Post intervention and after follow up scores on PCOS-QOL scale.

	Mean	Std. Deviation	Z	p-value
PCOSQOL POST	26.70	3.789	-2.605	.009
PCOSQOL FOLLOW UP	28.57	3.370		

RESULTS

The current study was done to study the efficacy of Cognitive Behaviour Therapy on reducing Depressive and anxiety symptoms accompanied by disruptions in sleep patterns contributing to improvement in QoL in patients with PCOS. The research study was conducted in the Dayanand Medical College & Hospital at department of Clinical Psychology, Ludhiana among 30 participants diagnosed with PCOS as per Rotterdam criteria. The participants were initially assessed on Hamilton depression rating scale (HDRS), Hamilton anxiety rating scale (HARS), Polycystic Ovarian Syndrome- Quality of Life scale (PCOS-QoL) and Pittsburgh Sleep Quality Index (PSQI) in baseline assessment prior to intervention. Individual sessions of approximately 70 minutes were conducted for 12 weeks. The data was further analyzed through SPSS. The results obtained are as follows:

Table 1 shows the distribution of age of participants where 40% of the participants belonged to an age range of 18 years to upto 24 years (N=12), 33.33% belonged to an age range of 25 years to 30 years (N=10), 26.7 % belonged to an age range of 31 years to 35 years (N=8).

Table 2 shows the distribution of educational qualification of participants where 3.3% of them were graduate (N=1), 6.7% have educated up to Intermediate (N=2), 33.3% have done High school certification (N=10), 33.3% have done their Middle school certification (N=10) and 23.3% have passed their Primary school certification.

Table 3 shows the distribution of occupational status of participants where 3.3% were Semi-skilled/ skilled worker (N=1), 40% were unemployed (N=12), 6.7% were other (N=2), 16.7% were professional (N=5) and 33.3% were students (N=10).

Table 4 shows the distribution of family type of participants where 76.7% belonged to nuclear family while and 23.3% belonged to Joint family.

Table 5 shows the distribution of occupational status of the Head of the family of the participants where 33.3% were Unemployed (N=10), 13.3% were doing elementary occupation (N=4), 43.3% were Plant and machine operator (N=13), 6.7% were Craft and related trade worker (N=2) and 3.3% were skilled/ shop/market workers (N=1).

Table 6 shows the distribution of Educational status of the Head of the family of the participants where 6.7% had done professional course or honors (N=2), 33.3% were graduate (N=10), 13.3% were Intermediate or diploma holder (N=4), 3.3% had done high school certification (N=1) and 20 % had done middle school certification (N=6), 16.7% had done primary school certification (N=5) and 3.4 % were illiterate (N=2).

Table 7 shows the distribution of socio economic status of the participants where 33.3% belong to Upper class family (N=10), 40% belong to Upper middle class family (N=12), 13.3% belong to Lower middle class family (N=4), 13.3% belong to Upper lower class family (N=4).

Table 8 shows the comparison of Pre and Post intervention scores of participants on depression as measured by HDRS. There is a decrease in the scores from pre- treatment (mean=15.80) to post treatment (mean= 7.60). The t value (6.44) and the p-value (0.001) both indicate statistical significance. The mean difference is 8.200, suggesting a notable reduction in the depression scores post treatment.

Table 9 reflects the comparison of Post and follow up intervention scores of participants on depression as measured by HDRS. The p-value (0.069) with a t-value of 1.890 indicates that this observed difference in HDRS scores between pre- and post-treatment evidence

that the CBT intervention had a marginally significant effect on reducing depressive symptoms as measured by the Hamilton Depression Rating Scale. The reduction in HRDS scores, while not statistically significant at the conventional level ($p < 0.05$) with the difference in mean scores observed pre and post intervention being 1.367 and a standard deviation of 3.961, indicated a reduction in depressive symptoms following the treatment suggesting a potential beneficial effect of the treatment on depressive symptoms.

Table 10 depicts the comparison of Pre and Post intervention scores of participants on anxiety as measured by HARS. The difference in mean scores observed pre intervention and post intervention is 8.10, with a standard deviation of 7.102, indicating an improvement in anxiety symptoms after the intervention where the mean HARS score decreased from 15.97 (pre-treatment) to 7.87 (post-treatment). The statistically significant p-value (0.001) indicates that this observed difference in HARS scores between pre- and post-treatment evidence that the CBT intervention had a significant effect on reducing anxiety symptoms as measured by the Hamilton Anxiety Rating Scale.

Table 11 indicates the comparison of Post and follow up intervention scores of participants on anxiety as measured by HARS. The mean HARS score decreased from 7.87 (post-treatment) to 6.43 (follow-up), as indicated by the mean difference between post-treatment scores and follow-up scores being 1.433, with a standard deviation (SD) of 4.493. The p-value of 0.091 suggests that the difference in HARS scores is not statistically significant ($p < 0.05$) indicating that the observed reduction in anxiety levels from post-treatment to follow-up probably might not be strong enough to confidently conclude statistical significance based on the used sample.

Table 12 depicts the comparison of Pre and Post intervention scores of participants on Sleep quality as measured by PSQI. For Sleep disturbances, a negative Z score of -3.228 and the p-value (0.001)

indicates a statistically significant difference between the two groups suggesting a significant improvement in sleep quality following the intervention where the mean PSQI score before the intervention was 8.03, with a standard deviation of 4.650. After the intervention, the mean score decreased to 4.50, with a standard deviation of 3.350.

Table 13 depicts the comparison of Post intervention and follow up scores of participants on Sleep quality as measured by PSQI. A z score of -1.352 suggests and the p-value (0.176) indicates a difference between the two groups suggesting an improvement in sleep quality following the intervention where a p-value of 0.176 is not typically statistically significant.

Table 14 depicts the comparison of Pre intervention and Post intervention scores of Emotional domain of PCOS-QOL scale. The findings suggests that the mean (7.50) for cases with worsened Emotion quality is significantly lower (N=1) than the cases with improved Emotions (N=25) with mean = 13.74. Given that a score of 1 indicates poor functioning and 7 indicates optimal functioning, the increase in mean score from 4.13 to 5.57 suggests a notable improvement in functioning levels.

The statistically significant negative Z-score of -4.357 with a p-value of < 0.001 confirms that likelihood of this substantial difference occurring randomly is low. Therefore, it is concluded that the intervention had a significant effect on enhancing functioning levels. The predominance of positive ranks suggests that, in the majority of cases (25 cases), there was an improvement or increase in values from pre-treatment to post-treatment.

Table 15 depicts the comparison of Post intervention and after follow up scores of Emotional domain of PCOS-QOL scale. Follow-up has a higher mean score of 5.97 compared to scores obtained post-treatment with a mean score of 5.57 indicating an improvement in scores from

post-treatment to follow-up where higher scores represent a more favorable outcome. The statistically significant p-value (0.019) and z value (-2.355) suggest a positive response to the CBT intervention.

Table 16 depicts the comparison of Pre intervention and Post intervention scores of Body image domain of PCOS-QOL scale. The increase from 4.40 to 5.47 with a standard deviation of 1.754 suggests a notable improvement in functioning following the treatment intervention. The Z-value of -3.559 and $p < 0.001$ indicate that the observed difference in functioning levels before and after treatment is statistically significant.

Table 17 shows the comparison of scores on Body image domain administered Post intervention and after follow up on PCOS-QOL scale. A statistical difference between post intervention and follow up scores ($p = 0.017$) is implicated with an effect size of $r = 0.6$. The z value (2.4) and the p-value (<0.05) indicate statistical significance suggesting a positive impact of CBT intervention on quality of life for individuals with PCOS. It is further evidenced that the observed change in PCOSQOL scores on Body image domain is not attributable to random variation.

Table 18 depicts the comparison of Pre intervention and Post intervention scores on Weight domain of PCOS-QOL scale. The positive rank is observed to be higher with a mean of 12 for N=18 than the negative rank with a mean of 5 for N=3. A Z score of -3.559 at p-value <0.001 indicates a significant deviation suggesting that overall the CBT treatment resulted in an improvement in the outcome scores., with a notable improvement in scores for the majority of individuals.

Table 19 shows the comparison of scores on Weight domain administered Post intervention and after Follow up on PCOS-QOL scale. The p-value (0.0065) is greater than 0.05 and z value of 1.8 indicating that the difference in median is not statistically significant.

The moderate effect size (r = 0.4) suggests that there is still a noticeable association between Post intervention scores having a slightly higher median score compared to Post intervention scores. Though the improvement in scores is not statistically significant, the observed difference can be attributed to chance factors.

Table 20 shows the comparison of scores on Infertility domain administered Pre and Post intervention on PCOS-QOL scale. A statistical difference between Post intervention scores with higher mean score of 5.70 and follow up scores with a mean score of 4.90 (p = 0.006) is implicated indicating improvement in scores on the PCOS scale where higher scores reflects better outcomes. The z value (-2.722) and the p-value (<0.05) indicate statistical significance suggesting a positive impact of CBT intervention on quality of life for individuals with PCOS.

Table 21 shows the comparison of scores on Infertility domain administered Post intervention and after Follow up on PCOS-QOL scale. The p-value (0.0425) is greater than 0.05 indicating that the difference in median is not statistically significant. The (r = 0.2) suggests that there is still a noticeable association between post intervention and follow up scores with follow up scores having a slightly higher median score compared to post intervention scores. Though the improvement in scores is not statistically significant, the observed difference can be attributed to chance factors.

Table 22 shows the comparison of scores on Menstrual problem domain administered Pre and Post intervention on PCOS-QOL scale. The mean score of Pre intervention was higher with a mean score of 3.83 to post intervention with a mean score (5.03), suggests an improvement in scores from before to after treatment, where higher scores represent a more favourable outcome. The z value (-4.320) and p-value (<0.001) are statistically significant highlighting the

effectiveness of the treatment in enhancing the measured outcome where higher scores indicate a more positive response.

Table 23 shows the comparison of scores on Menstrual problem domain administered Post intervention and after Follow up on PCOS-QOL scale. The follow-up scores (Median = 6) are significantly higher than the post-treatment scores (Median = 5), indicating improvement over time. The Z-value of 0.8 indicates that the difference between both the groups is not statistically significant at a conventional alpha level (< 0.05). The effect size (r) of 0.425 suggests a small effect, indicating a modest improvement in functioning from post-intervention to follow-up.

Table 24 shows the comparison of PCOS-QOL scores Pre and Post intervention. There is an increase in the scores from pre- treatment (mean=21.20) to post treatment (mean= 26.70). The z value (-4.760) and the p-value (<0.001) both indicate statistical significance suggesting a positive impact of CBT intervention on quality of life for individuals with PCOS. It is further evidences that the observed change in PCOSQOL scores is not attributable to random variation.

Table 25 shows the comparison of post intervention and after follow up scores on PCOS-QoL scale. Follow up score has a higher mean of 28.57 compared to post intervention score with a mean of 26.70 suggesting an improvement in scores from post-treatment to follow-up where higher scores represent a more favourable outcome. The statistically significant p-value (0.009) and z value (2.605) reflects a positive response to the intervention where higher scores reflect a better outcome over time.

DISCUSSION

The current study aimed to study the efficacy of Cognitive Behavior Therapy on reducing Depressive and anxiety symptoms accompanied by disruptions in sleep patterns contributing to improvement in QoL in patients with PCOS. The research study was conducted in the department of Clinical Psychology, Dayanand Medical College & Hospital, Ludhiana among 30 participants diagnosed with PCOS as per Rotterdam criteria. SDD was collected. The patients were then assessed on Hamilton depression rating scale (HDRS), Hamilton anxiety rating scale (HARS), Polycystic Ovarian Syndrome- Quality of Life scale (PCOS-QoL) and Pittsburgh Sleep Quality Index (PSQI) in baseline assessment prior to intervention. Individual sessions ranging from of 70 minutes (40 minutes CBT+ Relaxation) each were conducted for 12 weeks. Post CBT intervention, the baseline assessments were re-administered. The data collected was further organized into tables and examined utilizing SPSS. The results have been discussed as follows while taking in account the research evidence.

SOCIO-DEMOGRAPHIC VARIABLES

Data was described under the heads of age, occupation, family type and socio-economic status as well as educational qualification.

AGE:

The research study was conducted on participants aged between of 18 years to 35 years of age. The youngest participant was18 years old and the oldest was 35 years old. The distribution of age of participants where 40% of them belonged to an age range of 18 years to 24 years (N=12), 33.33% belonged to an age range of 25 years to 30 years (N=10) wile 26.7 % belonged to an age range of 31 years to 35 years (N=8). These findings were in coherence with previous literature evidence by Powel et al., 2022 [118], Saxena. P et al., 2021.[104] Tabassum et al., 2021.[96]

EDUCATIONAL QUALIFICATION:

The distribution of educational qualification of participants is in a way that among them, 3.3% of them were graduate (N=1), 6.7% have educated up to Intermediate (N=2), 33.3% have done High school certification (N=10), 33.3% have completed their Middle school certification (N=10) and 23.3% have passed ad qualified their Primary school certification. These findings were supported by Tabassum et al., 2021.[96], Wang, 2022 [126]

OCCUPATIONAL STATUS:

Percentage of participants who were Semi-skilled/ skilled worker was accounted to be 3.3% (N=1), 40% of them were unemployed (N=12), 6.7% had some other occupation (N=2), 16.7% were professionals (N=5) and 33.3% were students (N=10). These findings were supported by Dybciak, 2022 [127]; Stenhouse et al., 2017 [128]; Rubin et al., 2018.[129]

FAMILY TYPE:

The distribution of family type of participants indicates that 76.7% belonged to nuclear family while and 23.3% belonged to Joint family which is historically supported by Radha et al., 2016 [130]; George and Alex, 2021.[131]

SOCIO ECONOMIC STATUS:

The percentage of the participants belonging to Upper class family was 33.3% (N=10), 40% belong to Upper middle class family (N=12), 13.3% belong to Lower middle class family (N=4) and 13.3% belong to Upper lower class family (N=4).

PSYCHOLOGICAL MORBIDITY & CBT:

DEPRESSION-

The comparison of Pre and Post intervention scores of participants on depression as measured by HDRS reflects a decrease in the scores

from pre- treatment (mean=15.80) to post treatment (mean= 7.60). The t value (6.44) and the p-value (<0.001) both indicate statistical significance. The mean difference is 8.200, suggesting a notable reduction in the depression scores post treatment.

These discoveries indicate that difference is not likely due to random chance and are indicative of meaningful and substantial difference between the two groups.

CBT was instrumental in achieving the significant reduction in depression scores observed in the study as a therapeutic approach that focuses on identifying and modifying negative thought patterns and behaviors associated with depression. Though cognitive restructuring, identification and replacement of irrational thoughts with more realistic ones had contributed to a shift in perceptions and attitudes. Behavioral activation has improved the engagement in pleasurable activities providing a sense of accomplishment and pleasure counteracting the depressive symptoms.

Previous research in the same field also supports our findings, as can be seen through Lores et al. 2020 [133]; Rofey et al., 2007 [54] and Tang et al., 2022.[113]

At the follow up assessment for depression domain of Psychological morbidity, The p-value (0.069) with a t value of 1.890 indicates that this observed difference in HDRS scores between post-treatment and after follow up evidenced that the CBT intervention had a marginally significant effect on reducing depressive symptoms as measured by the Hamilton Depression Rating Scale.

The reduction in HRDS scores, while not statistically significant at the conventional level ($p < 0.05$) the difference in mean scores observed pre intervention and post intervention is 1.367, with a standard deviation of 3.961, indicating a reduction in depressive symptoms

following the treatment suggesting a hidden beneficial effect of the treatment on depressive symptoms.

Study done by Majidzadeh et al., 2023 [125]; Lores et al., 2020 [132] demonstrated that CBT can be particularly effective in reduction of psychological morbidity.

ANXIETY-

For anxiety domain of Psychological morbidity, the results show a notable contrast between the levels of anxiety before and after the intervention, with a mean score of 8.10 and a standard deviation of 7.102, suggesting an improvement in anxiety symptoms following the intervention. The average HARS score decreased from 15.97 before treatment to 7.87 after treatment, indicating a significant reduction in anxiety symptoms. The p-value of 0.001 with a t value of 6.247, further supports the conclusion that the CBT intervention had a substantial impact on alleviating anxiety symptoms as measured by the Hamilton Anxiety Rating Scale which is rendered crucial for addressing anxiety symptoms and improving overall well-being in patients with PCOS.

The components of CBT intervention including relaxation exercises and monitoring of thought diary further accounted for alleviation of anxiety symptoms as evidenced by the average score nearly halving after receiving the CBT intervention.

Recent researches has consistently demonstrated the superiority of CBT as can be seen by work of Majidzadeh et al., 2023.[125]

The comparison of Post and follow up intervention scores of participants on anxiety as measured by HARS indicate reduction in the mean score from 7.87 (post-treatment) to 6.43 (follow-up), with the mean difference being 1.433, with a standard deviation (SD) of 4.493. The p-value of 0.091 suggests that the difference in HARS scores is not statistically significant ($p < 0.05$) indicating that the observed

reduction in anxiety levels from post-treatment to follow-up may not be strong enough to confidently conclude statistical significance based on this sample. The findings implies the requirement of additional assessment with a larger sample size or longer follow-up duration may be necessary to better understand the sustained effects of the treatment on anxiety. The importance of ongoing support and follow up interventions to maintain the benefits achieved during the initial intervention phase has been implicated.

SLEEP DISTURBANCES & CBT:

Regarding sleep disturbances, a Z score of -3.228 and a p-value of 0.001 demonstrate a statistically significant contrast between the two groups, indicating a notable enhancement in sleep quality post-intervention. Before the intervention, the mean PSQI score stood at 8.03 with a standard deviation of 4.650. Post-intervention, the mean score decreased to 4.50, with a standard deviation of 3.350.

The findings reveal that the observed difference in PSQI scores between pre- and post-intervention is unlikely to have occurred by chance.

Therefore, it can be summarized that the intervention had a significant effect on improving sleep quality as measured by the PSQI. The current findings were silence with previous findings in the field by Martínez et al., 2013 [133]; Espie et al., 2020.[134]

Additionally, the decrease in standard deviation from 4.650 to 3.350 post-intervention indicating a potential decrease in variability among participants' sleep quality score further supporting the notion of improvement post CBT intervention.

Post follow up assessment, a z score of -1.352 and the p-value (0.176) indicates a difference between the two groups suggesting an improvement in sleep quality following the intervention where a p-value

of 0.176 is not typically considered statistically significant according to conventional thresholds (usually set at 0.05 or lower).

Despite the lack of statistical significance, the descriptive statistics suggest a tendency toward enhanced sleep quality following the intervention where the observed decrease in mean PSQI scores from 8.03 before the intervention to 4.50.

Further investigation with different analytical approaches or long term follow-up period is required to capture significant changes in sleep quality where improvement in sleep habits and patterns may require more time to be apparently noticeable and sustained and could become more conclusive evidence of the intervention's effect on sleep quality.

The results of significant improvement in sleep quality post CBT intervention were supported by Teo et al., 2022.[135]

QUALITY OF LIFE & CBT:

EMOTIONAL DOMAIN-

For Emotional domain, tthe findings of the research indicate a significant improvement in functioning following the intervention. Before the intervention, the mean score for functioning stood at 4.13, with a standard deviation of 1.137. After the intervention, the mean score increased to 5.57, with a standard deviation of 0.728. Given that a score of 1 indicates poor functioning and 7 indicates optimal functioning, the increase in mean score from 4.13 to 5.57 suggests a notable improvement in functioning levels.

The statistically significant Z-score of -4.357 with a p-value of <0.001 confirms that likelihood of such a substantial difference occurring randomly is extremely low. Therefore, it can be further concluded that the intervention had a significant effect on enhancing functioning levels.

CBT played a crucial role in reducing emotional disturbances as measured by the PCOSQOL (Polycystic Ovary Syndrome Quality of Life) scale where therapeutic practices of Emotion Regulation equipped individuals with skills to manage intense emotions associated with PCOS-related challenges and helping them learn effective ways to manage infertility concerns, navigate social situations impacted by PCOS symptoms, or cope with hormonal fluctuations which further contribute to changes emotional domain.

After follow up, the statistically significant p-value (0.019) and z value (-2.355) suggest a positive response to the CBT intervention. As the emotional domain of the PCOS-QOL scale is the main metric used to assess emotional well-being, it plays a key role in addressing emotional distress in patients with PCOS.

The findings reveal higher mean score at follow-up reflecting a more favourable emotional outcome, indicating sustained benefits beyond the initial intervention period.

One of the most significant improvements observed was in emotional well-being. Participants reported reduced anxiety, depression, and stress levels post-intervention, reflecting the effectiveness of CBT techniques in addressing negative thought patterns and emotional distress associated with PCOS.

This corresponds with the recent literature showcasing the efficacy of CBT contributing to improvement of Quality of Life on emotional domain done by Cooney et al., 2017 [48]; Kite et al., 2021.[136]

BODY IMAGE DOMAIN-

For Body image domain, the result reflects an increase in scores from pre- treatment. The mean score of 4.40 suggests that, on average, participants' functioning level before treatment was slightly above the mid-range of the scale (where 1 represents poor functioning and 7

represents optimal functioning). The mean score of 5.47 after treatment indicates a significant increase in functioning level compared to before treatment. The increase from 4.40 to 5.47 with a standard deviation of 1.754 suggests a notable improvement in functioning following the treatment intervention.

The Z-value of -3.559 and $p < 0.001$ indicate that the observed difference in functioning levels before and after treatment is statistically significant.

After follow up assessments on weight domain of PCOS-QOL scale,
$p = 0.065$ is implicated with an effect size of $r = 0.4$ and and z value of 1.8. The p-value (<0.05) and z value of 1.8 indicate the observation is not statistically significant.

It is further evidenced that the observed change in PCOSQOL scores on Body image domain is not attributable to random variation where techniques of Cognitive Restructuring helped the patients identify and challenge negative thoughts and beliefs related to PCOS symptoms. For example, participants may possess distorted beliefs about their self-worth or femininity due to symptoms hirsutism. CBT techniques can assist in reframing these thoughts to promote more adaptive and realistic perspectives.

The findings are supported by the existing literature as evidenced by the study done by Tang et al., 2022 [113]; Kite et al., 2021.[136]

WEIGHT DOMAIN-

For Weight domain, the comparative analysis before and post treatment reveals that the CBT intervention led to a statistically significant improvement in participants' functioning levels, as evidenced by the increase in mean score from 4.90 (before treatment) to 5.70 (after treatment) where greater scores indicate better functioning.

The findings suggest that the treatment was effective in enhancing participants' functioning towards more optimal levels, with a reduced variability in functioning levels post-treatment. A Z score of -2.722 at p-value <0.001 indicates a statistically significant deviation suggesting that overall the CBT treatment had a positive effect on the outcome scores, with a notable improvement in scores for the majority of individuals.

The observed improvement in this domain scores is unlikely to be due to chance, supporting the effectiveness of CBT in weight reduction.
These results provide evidence supporting the efficacy of the treatment intervention in improving participants' functioning. These findings are furthermore corroborated by study done by George et al., 2021 [131]; Cooney at al., 2017.[48]

Post follow up, the moderate effect size (r = 0.4) suggests that there is still a noticeable association between Post intervention scores having a slightly higher median score compared to Post intervention scores.
The p-value (0.06) is greater than 0.05 indicating that the difference in median is not statistically significant. Though the improvement in scores is not statistically significant, the observed difference can be attributed to chance factors.

CBT interventions addressing weight concerns resulted in improved perceptions of physical health and reduced anxiety related to weight management. Participants reported better adherence to lifestyle modifications and increased motivation for health-promoting behaviors.
The findings indicate that the effectiveness of CBT can be further evidenced and strengthened with longer follow-up and larger sample size. Longer-term follow up would be helpful given known difficulties with weight loss maintenance.

This concurs with recent research demonstrating the effectiveness of intervention in reduction of weight projecting towards lasting effect of

CBT beyond the immediate post intermediate period as done by Jiskoot et al., 2022 [137]; Thomson et al., 2009.[138]

INFERTILITY DOMAIN-

The comparison of scores on Infertility domain administered Pre and Post intervention reveals a statistical difference with higher mean score of 5.70 post intervention and with a mean score of 4.90 before intervention ($p = 0.006$) as implicated indicating improvement in scores on the PCOS scale where higher scores reflects better outcomes. The z value (-2.722) and the p-value (<0.05) indicate statistical significance suggesting a positive impact of CBT intervention on quality of life for individuals with PCOS. Study done by Majidzadeh et al, 2023 [125] further supports the results of the current findings.

After follow up, the median score of 6.5 for both post intervention and after follow up suggests that participants' functioning level, on average, is toward the optimal end of the scale. The p-value (0.425) is greater than 0.05 indicating that the difference in median is not statistically significant with a moderate effect size ($r = 0.2$) suggesting that there is still a noticeable association between both the groups with follow up having a slightly higher median score compared to post intervention scores.

Even though the intervention did not result in a statistically significant change in functioning scores, the overall level of functioning remained relatively high throughout. The result emphasizes the relevance of ongoing support and follow up interventions to perpetuate the benefits achieved during the initial intervention phase.

Findings by Tang et al, 2022 [113] are congruent with the findings of the current research.

MENSTRUAL DISTURBANCES DOMAIN-

For Menstrual problem domain, the mean score increased statistically significantly from Pre intervention (mean score = 3.83) to post intervention (mean score = 5.03). The z value (-4.320) and <0.001 are statistically significant highlighting the effectiveness of the treatment in enhancing the measured outcome where higher scores indicate a more positive response.

A strong and meaningful improvement due to the treatment intervention is emphasized further contributing to the significance of the CBT intervention in improving menstrual health as implicated by both the current study and supporting evidence from Majidzadeh et al. 2023.[125] Participants reported reduced distress related to infertility concerns, menstrual irregularities, and other reproductive issues post-intervention. CBT interventions likely provided coping strategies and cognitive restructuring techniques to manage these challenges and alleviate associated distress.

These findings add to the growing body of evidence in support of effective interventions for menstrual health and overall well-being.

Post follow up, the comparison of scores on Menstrual problem domain administered Post intervention and after Follow up on PCOS-QOL scale suggests that the follow-up scores (Median = 6) are significantly higher than the post-treatment scores (Median = 5), indicating improvement over time. The Z-value of 0.8 indicates that the difference between both the groups is not statistically significant at a conventional alpha level (< 0.05).

The small effect size (r) suggests that while there is a trend of improvement in functioning, the magnitude of this improvement is relatively modest. Given the non-significant Z-value, further investigation or consideration of other factors influencing the outcomes may be warranted to fully understand the observed changes in

functioning over time. These findings align with the study done by Cooney et al. 2017 [48], Tang et al., 2022.[113]

QUALITY OF LIFE & CBT

For QoL as assessed by PCOS-QOL, the comparison of PCOS-QOL scores Pre and Post intervention indicate an increase in the scores from pre- treatment (mean=21.20) to post treatment (mean= 26.70).
The z value (-4.760) and the p-value (<0.001) both indicate statistical significance suggesting a positive impact of CBT intervention on quality of life for individuals with PCOS. It is further evidenced that the observed change in PCOSQOL scores is not attributable to random variation.

A potential moderating effect of CBT intervention on overall Quality of Life in patients with PCOS is remarked as established by the relevance of using a validated and comprehensive measure like the PCOS-QOL scale to capture the multidimensional impact of PCOS on patients' lives consisting of domains of Emotional problems, Body image, Weight, Infertility and Weight.

Follow up score has a higher mean of 26.70 post treatment compared to a mean of 21.20 suggesting an improvement in scores from post-treatment to follow-up where higher scores represent a more favourable outcome. The statistically significant p-value (0.009) and z value (2.605) reflects a positive response to the intervention where higher scores reflect a better outcome over time.

The findings reveal a consistent and significant improvement in QOL across all domains following the CBT intervention. The study's notable finding is the across-the-board improvement in PCOS-QOL domain scores post-intervention.

Each domain of the PCOS-QOL scale showed statistically significant enhancements. This comprehensive improvement underscores the holistic impact of CBT on multiple aspects of individuals' lives affected by PCOS.

Findings by Dey., 2018 [98]; Cooney at al., 2017 [48]; are consistent with the findings of the current research.

LIMITATIONS

1. There was no control group in order to compare it with the study population.
2. Size of the study was small.
3. The current study was a hospital based study in an urban region of Punjab. This might limit the generalizability of the study to Indian population.
4. Interpreting changes in PCOSQOL scores in the context of combined CBT and pharmacological interventions can be complex, requiring careful consideration of confounding variables and interaction effects between treatment modalities. It may not specifically elucidate the mechanisms through which CBT and pharmacological interventions exert their effects individualistically.
5. Despite having a significant improvement in weight concerns domain as assessed on PCOS-QoL, a differential improvement in other metabolic parameters, androgens, or inflammatory markers could not be substantially translated. Research have demonstrated that anti-inflammatory effects of weight loss may not be observed for up to 6 months for which the current intervention timeline may not have been sufficient.

SUMMARY AND CONCLUSION

The current study aimed to investigate the efficacy of Cognitive Behavior Therapy in alleviating symptoms of depression and anxiety, as well as addressing sleep disruptions contributing to improvement in Quality of Life in patients with PCOS. The study was conducted in the department of Clinical Psychology, Dayanand Medical College & Hospital, Ludhiana among 30 participants diagnosed with PCOS as per Rotterdam criteria. Socio-demographic data was collected. The participants were then assessed on Hamilton depression rating scale (HDRS), Hamilton anxiety rating scale (HARS), Polycystic Ovarian Syndrome- Quality of Life scale (PCOS-QoL) and Pittsburgh Sleep Quality Index (PSQI) in baseline assessment prior to intervention. Individual sessions ranging from of 70 minutes (40 minutes CBT+ Relaxation) each were conducted for 12 weeks. Post CBT intervention, the baseline assessments were re-administered. The data collected was then tabulated and analysed using SPSS. The results obtained are summarized as follows:

The distribution of age of participants aged between 18 years to 35 years of age, where 40% of them belonged to an age range of 18 years to 24 years (N=12), 33.33% belonged to an age range of 25 years to 30 years (N=10) wile 26.7 % belonged to an age range of 31 years to 35 years (N=8).

The distribution of educational qualification of participants is in a way that 3.3% of them were graduate (N=1), 6.7% have educated up to Intermediate (N=2), 33.3% have done High school certification (N=10), 33.3% have qualified their Middle school certification (N=10) and 23.3% have done their Primary school certification.

Percentage of participants who were Semi-skilled/ skilled worker was accounted to be 3.3% (N=1), 40% of them were unemployed (N=12),

6.7% had some other occupation (N=2), 16.7% were professionals (N=5) and 33.3% were students (N=10).

The distribution of family type of participants indicates that 76.7% belonged to nuclear family while and 23.3% belonged to Joint family.
The percentage of the participants belonging to Upper class family was 33.3% (N=10), 40% belong to Upper middle class family (N=12), 13.3% belong to Lower middle class family (N=4) and 13.3% belong to Upper lower class family (N=4).

For Psychological morbidity (depression domain), the mean difference of 8.200 between pre- intervention and post intervention measure with the p-value (<0.001) and t value of 6.444 indicated statistical significance suggesting a notable reduction in the depression scores post treatment.

For Psychological morbidity (Depression domain), at the follow up assessment, the p-value (0.069) with a t-value of 1.890 was not statistically significant and indicated that the CBT intervention had a marginally significant effect on reducing depressive symptoms.

For Psychological morbidity (Anxiety domain), there is a statistically significant difference in mean scores observed pre and post intervention. The statistically significant p-value of 0.001 indicates substantial impact of CBT on alleviating anxiety symptoms.

For Psychological morbidity (Anxiety domain), the post follow up, the mean HARS score decreased from 7.87 (post treatment) to 6.43 (follow-up), with a standard deviation (SD) of 4.493. The results indicate the p-value of 0.091 suggesting that the difference in HARS scores is not statistically significant.

For Sleep disturbances, a negative Z score of -3.228 and the p-value (0.001) indicates a statistically significant difference between the pre

and post intervention suggesting a significant improvement in sleep quality.

For Sleep disturbances, post follow up assessment, Z score of -1.352 and the p-value (0.176) indicates improvement in sleep quality following the intervention which is not statistically significant. The descriptive statistics indicate an improved sleep quality following the CBT intervention where the observed decrease in mean PSQI scores was from 8.03 post intervention to 4.50 after follow up.

For Emotional domain of Quality of life, there is a statistically significant difference between the pre and post intervention measure. The z score of -4.357 with a p-value of <0.001 indicate statistical significance.

For Emotional domain of Quality of life, the comparison of Post intervention and after follow up scores of reflects an improvement in scores where follow-up has a higher mean score of 5.97 compared to scores obtained post-treatment with a mean score of 5.57 where higher scores represent a more favourable outcome. The statistically significant p-value (0.019) and z value (-2.355) suggest a positive response to the CBT intervention.

For Body image domain of Quality of life, the result reflects a statistically significant increase in scores from pre- treatment to post treatment. The Z-value of -3.559 and a p-value < 0.001 indicate that the observed difference in functioning levels before and after treatment is statistically significant.

For Body image domain of Quality of life, after follow up assessments reveal a statistically significant difference (p = 0.017) with an effect size of r = 0.6.at a z value (2.4) indicating statistical significance suggesting a positive impact of CBT intervention on quality of life for individuals with PCOS post intervention and after follow up.

For Weight domain of Quality of life, the comparative analysis before and post treatment reveals that the CBT intervention led to a statistically significant improvement in participants' functioning levels, as evidenced by the statistically significant increase in mean score. A z score of -3.559 at p-value <0.001 indicates a statistically significant findings.

For Weight domain of Quality of life, post follow up measure suggests the p-value (0.0065) with a moderate effect size (r = 0.4) is not statistically significant.

For Infertility domain of Quality of life, there is a statistically significant difference between the pre and post intervention measure. The (p = 0.006) and z value (-2.722) indicate statistical significance.

For Infertility domain of Quality of life, after follow up assessments, the difference in median with the p-value (0.425) was not statistically significant. A moderate effect size (r = 0.2) suggested a noticeable association between both the groups with follow up having a slightly higher median score compared to post intervention scores.

For Menstrual problem domain of Quality of life, the mean score further increased significantly from Pre intervention (mean score = 3.83) to post intervention (mean score = 5.03). The z value (-4.320) and p-value (<0.001) are statistically significant.

For Menstrual domain of Quality of Life, post follow up, the comparison of scores administered Post intervention and after Follow up suggests higher median post intervention (Median = 6) than the follow up phase (Median = 5), indicating improvement over time. The Z-value of 0.8 indicates that the difference between both the groups is not statistically significant at a conventional alpha level. The small effect size (r=0.2) suggests that while there is a trend of improvement in functioning, the magnitude of this improvement is relatively modest.

For Quality of Life (Total),in comparison of PCOS-QOL scores Pre and Post intervention indicate statistically significant difference. The z value (-4.760) and the p-value (<0.001) both indicate statistical significance suggesting a positive impact of CBT intervention on QoL for individuals with PCOS.

For PCOSQOL Total, follow up score has a higher mean of 28.57 compared to post intervention score with a mean of 26.70 suggesting an improvement in scores from post-treatment to follow-up where higher scores represent a more favourable outcome. The statistically significant p-value (0.009) and z value (-2.605) reflects a positive response to the intervention where higher scores reflect a better outcome over time.

In conclusion, the findings highlight the efficacy of Cognitive Behavioural Therapy (CBT) in addressing psychological morbidity, sleep disturbances, and various dimensions of quality of life in individuals with PCOS. While immediate post-intervention improvements were generally significant across measures, the maintenance of these benefits at follow-up varied.. The study fills a crucial research gap by exploring the impact of CBT on addressing psychological morbidity, sleep disturbances, and overall quality of life in individuals with PCOS within the specific cultural and regional context of Punjab where the results indicated that the use of CBT showed promising results as a therapeutic intervention in the field of PCOS. Continued support and individualized interventions may be warranted to optimize long-term outcomes and ensure sustained improvements in quality of life for individuals with PCOS.

FUTURE DIRECTIONS

Cognitive Behavioural Therapy (CBT) has demonstrated significant efficacy in treating psychological morbidity and addressing sleep disturbances among females, diagnosed with PCOS, thereby contributing to enhanced QoL. The exploration of implementing CBT as a preventive and protective measure post-infertility concerns, aimed at promoting neonatal health and augmenting women's psychological well-being, has been suggested further. PCOS management necessitates a multidisciplinary treatment approach, wherein CBT shows promising therapeutic potential in recognizing psychological morbidity and its impact on other coexisting conditions. Comprehensive assessments of the synergistic effects of combining CBT with medical and lifestyle interventions highlight improvements in overall treatment outcomes and quality of life. Additionally, exploring the use of technology-based CBT interventions to enhance accessibility and scalability of support for women in psychological domain with PCOS could extend the applicability of CBT across various disorders, thereby promoting sustained medical adherence.

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SOCIO-DEMOGRAPHIC PROFORMA

S.NO: - **Date:**

1. NAME:

2. AGE:

3. MRD.NO: -

4. Education-

a) Illiterate b) Up to Matric**.** c) 10th d) 12th e) Graduate

f) Post graduate

5. Occupation-

a) Farmer/Clerical/Shopkeeper b) Semi-skilled/skilled worker c) Unemployed d) Other

e) Professional f) Student

6. Address- a) Urban b) Rural

7. Contact no.-

8. Family Type- a) Nuclear b) Joint

9. Education of the Head of the family

Profession or honors

Graduate

Intermediate or diploma

High school certificate

Middle school certificate

Primary school certificate

Illiterate

10. Occupation of the head

Legislators, senior officials, and managers

Professionals

Technicians and associate professionals

Clerks

Skilled workers and shop and market sales workers

Skilled agricultural and fishery workers

Craft and related trade workers

Plant and machine operators and assemblers

Elementary occupation

Unemployed

11. Monthly income of the family

- ≥20,482
- 10,241–20,481
- 7681–10,240
- 5120–7680
- 3072–5119
- 1034–3071
- ≤1033

12. Socio economic status

Upper

Upper middle

Lower middle

Upper lower

Lower

13. Time since diagnosis

14. Pharmacological treatment history

15. SCALES:

Hamilton depression rating scale (HDRS)

Hamilton anxiety rating scale (HARS)

Pittsburgh Sleep Quality Index (PSQI)	
Domain	Component Score
Sleep duration	
Sleep disturbance	
Latency	
Daytime sleep	
Sleep Dysfunction	
Sleep quality	
Medication	
Global score	

Polycystic Ovary Syndrome Questionnaire (PCOSQ)	
Domain	Score
Emotional domain	
Hirsutism	
Weight	
Infertility	
Irregular menstruation	
Overall	

16. PSYCHOTHERAPEUTIC INTERVENTION

	HDRS	HARS	PSQI	POCS-QOL					Total
				E	B	W	I	M	
Pre intervention scores									
Session 1									
Session 2									
Session 3									
Session 4									
Session 5									
Session 6									
Session 7									
Session 8									
Session 9									
Session 10									
Session 11									
Session 12									
Post intervention scores									
Follow up Scores									

Hamilton Depression Rating Scale (HDRS)

Reference: **Hamilton M. A rating scale for depression. J Neurol Neurosurg Psychiatry 1960; 23:56-62**

Rating Clinician-rated

Administration time 20–30 minutes

Main purpose To assess severity of, and change in, depressive symptoms

Population Adults

Commentary

The HDRS (also known as the Ham-D) is the most widely used clinician-administered depression assessment scale. The original version contains 17 items ($HDRS_{17}$) pertaining to symptoms of depression experienced over the past week. Although the scale was designed for completion after an unstructured clinical interview, there are now semi-structured interview guides available. The HDRS was originally developed for hospital inpatients, thus the emphasis on melancholic and physical symptoms of depression. A later 21-item version ($HDRS_{21}$) included 4 items intended to subtype the depression, but which are sometimes, incorrectly, used to rate severity. A limitation of the HDRS is that atypical symptoms of depression (e.g., hypersomnia, hyperphagia) are not assessed (see SIGH-SAD, page 55).

Scoring

Method for scoring varies by version. For the $HDRS_{17}$, a score of 0–7 is generally accepted to be within the normal range (or in clinical remission), while a score of 20 or higher (indicating at least moderate severity) is usually required for entry into a clinical trial.

Versions

The scale has been translated into a number of languages including French, German, Italian, Thai, and Turkish. As well, there is an Interactive Voice Response version (IVR), a Seasonal Affective Disorder version (SIGH-SAD, see page 55), and a Structured Interview Version (HDS-SIV). Numerous versions with varying lengths include the HDRS17, HDRS21, HDRS29, HDRS8, HDRS6, HDRS24, and HDRS7 (see page 30).

Additional references

Hamilton M. Development of a rating scale for primary depressive illness. Br J Soc Clin Psychol 1967; 6(4):278-96.

Williams JB. A structured interview guide for the Hamilton Depression Rating Scale. Arch Gen Psychiatry 1988; 45(8):742-7.

Address for correspondence

The HDRS is in the public domain.

Hamilton Depression Rating Scale (HDRS)

PLEASE COMPLETE THE SCALE BASED ON A STRUCTURED INTERVIEW

Instructions: for each item select the one "cue" which best characterizes the patient. Be sure to record the answers in the appropriate spaces (positions 0 through 4).

1 **DEPRESSED MOOD** *(sadness, hopeless, helpless, worthless)*
- 0 |__| Absent.
- 1 |__| These feeling states indicated only on questioning.
- 2 |__| These feeling states spontaneously reported verbally.
- 3 |_| Communicates feeling states non-verbally, i.e. through facial expression, posture, voice and tendency to weep.
- 4 |_| Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication.

2 FEELINGS OF GUILT
- 0 |__| Absent.
- 1 |__| Self reproach, feels he/she has let people down.
- 2 |_| Ideas of guilt or rumination over past errors or sinful deeds.
- 3 |__| Present illness is a punishment. Delusions of guilt.
- 4 |_| Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations.

3 SUICIDE

0 |__| Absent.
1 |__| Feels life is not worth living.
2 |_| Wishes he/she were dead or any thoughts of possible death to self.
3 |__| Ideas or gestures of suicide.
4 |__| Attempts at suicide (any serious attempt rate 4).

4 INSOMNIA: EARLY IN THE NIGHT

0 |__| No difficulty falling asleep.
1 |_| Complains of occasional difficulty falling asleep, i.e. more than ½ hour.
2 |__| Complains of nightly difficulty falling asleep.

5 INSOMNIA: MIDDLE OF THE NIGHT

0 |__| No difficulty.
1 |_| Patient complains of being restless and disturbed during the night.
2 |__| Waking during the night – any getting out of bed rates 2 (except for purposes of voiding).

6 INSOMNIA: EARLY HOURS OF THE MORNING

0 |__| No difficulty.
1 |_| Waking in early hours of the morning but goes back to sleep.
2 |__| Unable to fall asleep again if he/she gets out of bed.

7 WORK AND ACTIVITIES

0 |__| No difficulty.
1 |_| Thoughts and feelings of incapacity, fatigue or weakness related to activities, work or hobbies.
2 |_| Loss of interest in activity, hobbies or work – either directly reported by the patient or indirect in listlessness, indecision and vacillation (feels he/she has to push self to work or activities).
3 |__| Decrease in actual time spent in activities or decrease in productivity. Rate 3 if the patient does not spend at least three hours a day in activities (job or hobbies) excluding routine chores.
4 |_| Stopped working because of present illness. Rate 4 if patient engages in no activities except routine chores, or if patient fails to perform routine chores unassisted.

8 RETARDATION (slowness of thought and speech, impaired ability to concentrate, decreased motor activity)

0 |__| Normal speech and thought.
1 |__| Slight retardation during the interview.
2 |__| Obvious retardation during the interview.
3 |__| Interview difficult.
4 |__| Complete stupor.

9 AGITATION

0 |__| None.
1 |__| Fidgetiness.
2 |__| Playing with hands, hair, etc.
3 |__| Moving about, can't sit still.
4 |__| Hand wringing, nail biting, hair-pulling, biting of lips.

10 ANXIETY PSYCHIC

0 |__| No difficulty.
1 |__| Subjective tension and irritability.
2 |__| Worrying about minor matters.
3 |__| Apprehensive attitude apparent in face or speech.
4 |__| Fears expressed without questioning.

11 ANXIETY SOMATIC (physiological concomitants of anxiety) such as:

gastro-intestinal – dry mouth, wind, indigestion, diarrhea, cramps, belching
cardio-vascular – palpitations, headaches
respiratory – hyperventilation, sighing
urinary frequency
sweating

0 |__| Absent.
1 |__| Mild.
2 |__| Moderate.
3 |__| Severe.
4 |__| Incapacitating.

12 SOMATIC SYMPTOMS GASTRO-INTESTINAL

0 |__| None.
1 |_| Loss of appetite but eating without staff encouragement. Heavy feelings in abdomen.
2 |_| Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for gastro-intestinal symptoms.

13 GENERAL SOMATIC SYMPTOMS

0 |__| None.
1 |_| Heaviness in limbs, back or head. Backaches, headaches, muscle aches. Loss of energy and fatigability.
2 |__| Any clear-cut symptom rates 2.

14 GENITAL SYMPTOMS (symptoms such as loss of libido, menstrual disturbances)

0 |__| Absent.
1 |__| Mild.
2 |__| Severe.

15 HYPOCHONDRIASIS

0 |__| Not present.
1 |__| Self-absorption (bodily).
2 |__| Preoccupation with health.
3 |__| Frequent complaints, requests for help, etc.
4 |__| Hypochondriacal delusions.

16* LOSS OF WEIGHT *(RATE EITHER a OR b)

a) According to the patient:	**b) According to weekly measurements:**
0 |__| No weight loss.	0 |__| Less than 1 lb weight loss in week.
1 |__| Probable weight loss associated with present illness.	1 |_| Greater than 1 lb weight loss in week.
2 |_| Definite (according to patient) weight loss.	2 |_| Greater than 2 lb weight loss in week.
3 |__| Not assessed.	3 |_| Not assessed.

17 INSIGHT

0 |__| Acknowledges being depressed and ill.
1 |_| Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc.
2 |__| Denies being ill at all.

Total score: |__|__|

This scale is in the public domain.

Hamilton Anxiety Rating Scale (HAM-A)

Reference: **Hamilton M.The assessment of anxiety states by rating. Br J Med Psychol 1959; 32:50–55.**

Rating Clinician-rated

Administration time 10–15 minutes

Main purpose To assess the severity of symptoms of anxiety

Population Adults, adolescents and children

Commentary

The HAM-A was one of the first rating scales developed to measure the severity of anxiety symptoms, and is still widely used today in both clinical and research settings. The scale consists of 14 items, each defined by a series of symptoms, and measures both psychic anxiety (mental agitation and psychological distress) and somatic anxiety (physical complaints related to anxiety). Although the HAM-A remains widely used as an outcome measure in clinical trials, it has been criticized for its sometimes poor ability to discriminate between anxiolytic and antidepressant effects, and somatic anxiety versus somatic side effects. The HAM-A does not provide any standardized probe questions. Despite this, the reported levels of inter-rater reliability for the scale appear to be acceptable.

Scoring

Each item is scored on a scale of 0 (not present) to 4 (severe), with a total score range of 0–56, where <17 indicates mild severity, 18–24 mild to moderate severity and 25–30 moderate to severe.

Versions

The scale has been translated into: Cantonese for China, French and Spanish. An IVR version of the scale is available from Healthcare Technology Systems.

Additional references

Maier W, Buller R, Philipp M, Heuser I. The Hamilton Anxiety Scale: reliability, validity and sensitivity to change in anxiety and depressive disorders. J Affect Disord 1988;14(1):61–8.

Borkovec T and Costello E. Efficacy of applied relaxation and cognitive behavioral therapy in the treatment of generalized anxiety disorder. J Clin Consult Psychol 1993; 61(4):611–19

Address for correspondence

The HAM-A is in the public domain.

Hamilton Anxiety Rating Scale (HAM-A)

Below is a list of phrases that describe certain feeling that people have. Rate the patients by finding the answer which best describes the extent to which he/she has these conditions. Select one of the five responses for each of the fourteen questions.

0 = Not present, 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Very severe.

1 Anxious mood [0] [1] [2] [3] [4]

Worries, anticipation of the worst, fearful anticipation, irritability.

2 Tension [0] [1] [2] [3] [4]

Feelings of tension, fatigability, startle response, moved to tears easily, trembling, feelings of restlessness, inability to relax.

3 Fears [0] [1] [2] [3] [4]

Of dark, of strangers, of being left alone, of animals, of traffic, of crowds.

4 Insomnia [0] [1] [2] [3] [4]

Difficulty in falling asleep, broken sleep, unsatisfying sleep and fatigue on waking, dreams, nightmares, night terrors.

5 Intellectual [0] [1] [2] [3] [4]

Difficulty in concentration, poor memory.

6 Depressed mood [0] [1] [2] [3] [4]

Loss of interest, lack of pleasure in hobbies, depression, early waking, diurnal swing.

7 Somatic (muscular) [0] [1] [2] [3] [4]

Pains and aches, twitching, stiffness, myoclonic jerks, grinding of teeth, unsteady voice, increased muscular tone.

8 Somatic (sensory) [0] [1] [2] [3] [4]

Tinnitus, blurring of vision, hot and cold flushes, feelings of weakness, pricking sensation.

9 Cardiovascular symptoms [0] [1] [2] [3] [4]

Tachycardia, palpitations, pain in chest, throbbing of vessels, fainting feelings, missing beat.

10 Respiratory symptoms [0] [1] [2] [3] [4]

Pressure or constriction in chest, choking feelings, sighing, dyspnea.

11 Gastrointestinal symptoms [0] [1] [2] [3] [4]

Difficulty in swallowing, wind abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, borborygmi, looseness of bowels, loss of weight, constipation.

12 Genitourinary symptoms [0] [1] [2] [3] [4]

Frequency of micturition, urgency of micturition, amenorrhea, menorrhagia, development of frigidity, premature ejaculation, loss of libido, impotence.

13 Autonomic symptoms [0] [1] [2] [3] [4]

Dry mouth, flushing, pallor, tendency to sweat, giddiness, tension headache, raising of hair.

14 Behavior at interview [0] [1] [2] [3] [4]

Fidgeting, restlessness or pacing, tremor of hands, furrowed brow, strained face, sighing or rapid respiration, facial pallor, swallowing, etc.

Name:_____ Date: _____

Pittsburgh Sleep Quality Index (PSQI)

Instructions: The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. **Please answer all questions.**

1. During the past month, what time have you usually gone to bed at night? _____
2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night? _____
3. During the past month, what time have you usually gotten up in the morning? _____
4. During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spent in bed.) _____

5. During the past month, how often have you had trouble sleeping because you…	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
a. Cannot get to sleep within 30 minutes				
b. Wake up in the middle of the night or early morning				
c. Have to get up to use the bathroom				
d. Cannot breathe comfortably				
e. Cough or snore loudly				
f. Feel too cold				
g. Feel too hot				
h. Have bad dreams				
i. Have pain				
j. Other reason(s), please describe:				
6. During the past month, how often have you taken medicine to help you sleep (prescribed or "over the counter")?				
7. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?				
	No problem at all	Only a very slight problem	Somewhat of a problem	A very big problem
8. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?				
	Very good	Fairly good	Fairly bad	Very bad
9. During the past month, how would you rate your sleep quality overall?				

	No bed partner or room mate	Partner/room mate in other room	Partner in same room but not same bed	Partner in same bed
10. Do you have a bed partner or room mate?				
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
If you have a room mate or bed partner, ask him/her how often in the past month you have had:				
a. Loud snoring				
b. Long pauses between breaths while asleep				
c. Legs twitching or jerking while you sleep				
d. Episodes of disorientation or confusion during sleep				
e. Other restlessness while you sleep, please describe:				

Scoring the PSQI

The order of the PSQI items has been modified from the original order in order to fit the first 9 items (which are the only items that contribute to the total score) on a single page. Item 10, which is the second page of the scale, does not contribute to the PSQI score.

In scoring the PSQI, seven component scores are derived, each scored 0 (no difficulty) to 3 (severe difficulty). The component scores are summed to produce a global score (range 0 to 21). Higher scores indicate worse sleep quality.

Component 1: Subjective sleep quality—question 9

Response to Q9	Component 1 score
Very good	0
Fairly good	1
Fairly bad	2
Very bad	3

Component 1 score:_____

Component 2: Sleep latency—questions 2 and 5a

Response to Q2	Component 2/Q2 subscore
≤ 15 minutes	0
16-30 minutes	1
31-60 minutes	2
> 60 minutes	3

Response to Q5a	Component 2/Q5a subscore
Not during past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3

Sum of Q2 and Q5a subscores	Component 2 score
0	0
1-2	1
3-4	2
5-6	3

Component 2 score:_____

Component 3: Sleep duration—question 4

Response to Q4	Component 3 score
> 7 hours	0
6-7 hours	1
5-6 hours	2
< 5 hours	3

Component 3 score:_____

Component 4: Sleep efficiency—questions 1, 3, and 4

Sleep efficiency = (# hours slept/# hours in bed) X 100%

hours slept—question 4

hours in bed—calculated from responses to questions 1 and 3

Sleep efficiency	Component 4 score
> 85%	0
75-84%	1
65-74%	2
< 65%	3

Component 4 score:_____

Component 5: Sleep disturbance—questions 5b-5j

Questions 5b to 5j should be scored as follows:

Not during past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3

Sum of 5b to 5j scores	Component 5 score
0	0
1-9	1
10-18	2
19-27	3

Component 5 score:_____

Component 6: Use of sleep medication—question 6

Response to Q6	Component 6 score
Not during past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3

Component 6 score:_____

Component 7: Daytime dysfunction—questions 7 and 8

Response to Q7	Component 7/Q7 subscore
Not during past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3

Response to Q8	Component 7/Q8 subscore
No problem at all	0
Only a very slight problem	1
Somewhat of a problem	2
A very big problem	3

Sum of Q7 and Q8 subscores	Component 7 score
0	0
1-2	1
3-4	2
5-6	3

Component 7 score:_____

Global PSQI Score: Sum of seven component scores:_____

Copyright notice: The Pittsburgh Sleep Quality Index (PSQI) is copyrighted by Daniel J. Buysse, M.D. Permission has been granted to reproduce the scale on this website for clinicians to use in their practice and for researchers to use in non-industry studies. For other uses of the scale, the owner of the copyright should be contacted.

Citation: Buysse, DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ: The Pittsburgh Sleep Quality Index (PSQI): A new instrument for psychiatric research and practice. Psychiatry Research 28:193-213, 1989

Appendix 3: PCOSQ

Instructions: This questionnaire is designed for women with Polycystic Ovary Syndrome. In the questionnaire, we will refer to the Polycystic Ovary Syndrome by its initials: PCOS. The questions concern your health and health-related issues. Please respond to each question by checking the box with the rating that best reflects how you feel. For each question, you have seven rating options. Option 1 represents the greatest possible impairment, while Option 7 represents the least impairment. Choose only one option for each question. There is no right or wrong answer. Just choose the option that is closest to how you feel.

Date:

Study No:

Interview No: 1 / 2 PCOSQ

To what extent have you felt that growth of visible hair on your chin has been a problem for you during the **last two weeks:**

	A severe problem	A major problem	A moderate problem	Some problem	A little problem	Hardly any problem	No problem
Q1. Growth of visible hair on chin?	☐	☐	☐	☐	☐	☐	☐

During **the past two weeks,** how much of the time have you felt?

	All the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Hardly any of the time	None of the time
Q2. Depressed as a result of having PCOS?	☐	☐	☐	☐	☐	☐	☐
Q3. Concerned about being overweight?	☐	☐	☐	☐	☐	☐	☐
Q4. Easily tired?	☐	☐	☐	☐	☐	☐	☐

Q5. Concerned with infertility problems?	☐	☐	☐	☐	☐	☐	☐
Q6. Moody as a result of having PCOS?	☐	☐	☐	☐	☐	☐	☐

In addition to your last menstruation, how much were the following issues a problem for you?

	A severe problem	A major problem	A moderate problem	Some problem	A little problem	Hardly any problem	No problem
Q7. Headaches?	☐	☐	☐	☐	☐	☐	☐
Q8. Irregular menstrual periods?	☐	☐	☐	☐	☐	☐	☐

To what extent has growth of visible hair on your upper lip been a problem for you **the last two weeks?**

	A severe problem	A major problem	A moderate problem	Some problem	A little problem	Hardly any problem	No problem
Q9. Growth of visible hair on upper lip?	☐	☐	☐	☐	☐	☐	☐

During the **past two weeks,** how much of the time have you**:**

	All the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Hardly any of the time	None of the time
Q10. Had trouble dealing with your weight?	☐	☐	☐	☐	☐	☐	☐
Q11. Had low self-esteem as a result of having PCOS?	☐	☐	☐	☐	☐	☐	☐
Q12. Felt frustration in trying to lose weight?	☐	☐	☐	☐	☐	☐	☐
Q13. Felt afraid of not being able to have children?	☐	☐	☐	☐	☐	☐	☐
Q14. Felt frightened of getting cancer?	☐	☐	☐	☐	☐	☐	☐

Over the **last two weeks** to what extent the following issues have been a problem for you:

	A severe problem	A major problem	A moderate problem	Some problem	A little problem	Hardly any problem	No problem
Q15. Growth of visible hair on your face?	☐	☐	☐	☐	☐	☐	☐
Q16. Embarrassment about excessive body hair?	☐	☐	☐	☐	☐	☐	☐

During the **past two weeks** how much of the time have you been:

	All the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Hardly any of the time	None of the time
Q17. Worried about having PCOS?	☐	☐	☐	☐	☐	☐	☐
Q18. Self-conscious as a result of having PCOS?	☐	☐	☐	☐	☐	☐	☐

In relation to **<u>your last menstruation</u>**, how much the following issues were a problem for you:

	A severe problem	A major problem	A moderate problem	Some problem	A little problem	Hardly any problem	No problem
Q19. Abdominal bloating?	☐	☐	☐	☐	☐	☐	☐
Q20. Late menstrual period?	☐	☐	☐	☐	☐	☐	☐
Q21. Menstrual cramps?	☐	☐	☐	☐	☐	☐	☐

How much of the time during the **<u>last two weeks</u>** did you**:**

	All the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Hardly any of the time	None of the time
Q22. Feel like you are not sexy because of being overweight?	☐	☐	☐	☐	☐	☐	☐

Q23. Feel a lack of control over the situation with PCOS?	☐	☐	☐	☐	☐	☐	☐
Q24. Have difficulties staying at your ideal weight?	☐	☐	☐	☐	☐	☐	☐
Q25. Feel sad because of infertility problems?	☐	☐	☐	☐	☐	☐	☐

To what extent has growth of visible body hair been a problem for you the **last two weeks?**

	A severe problem	A major problem	A moderate problem	Some problem	A little problem	Hardly any problem	No problem
Q26. Growth of visible body hair?	☐	☐	☐	☐	☐	☐	☐

THIS QUESTIONNAIRE WAS DEVELOPED BY AND OBTAINED FROM:

L. Cronin, G. Guyatt, L. Griffith, E. Wong, R. Azziz, W. Futterweit, D. Cook, A. Dunaif. Development of a Health-Related Quality-of-Life Questionnaire (PCOSQ) for Women with Polycystic Ovary Syndrome (PCOS) Journal of Clinical Endocrinology and Metabolism 1998;83(6):1976-1986*

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SR. NO.	NAME	AGE	MRD.NO	EDUCATION	OCCUPATION	FAMILY TYPE	EDUCATION OF HEAD OF THE FAMILY	OCCUPATION OF THE HEAD OF THE FAMILY	MONTHLY INCOME OF THE FAMILY	SES
1	H.K	21	1528389	Intermediate/Diploma	Skilled workers and shop and market sales workers	Nuclear	Illiterate	legislators, senior official or managers	≤1033	upper class
2	S	21	1442600	High School Certificate	Plant and machine operators and assemblers	Nuclear	primary School Certificate	plant and machine operators and assemblers	1034–3071	upper middle class
3	G.A	26	1261788	Graduate	Skilled workers and shop and market sales workers	Nuclear	primary School Certificate	legislators, senior official or managers	≤1033	upper class
4	J.K	19	1607367	High School Certificate	Skilled workers and shop and market sales workers	Nuclear	Profession/Honours	elementary occupation	3072–5119	upper lower class
5	T	18	1610609	High School Certificate	Skilled workers and shop and market sales workers	Nuclear	Graduate	plant and machine operators and assemblers	1034–3071	upper middle class
6	R.K	35	39723	Intermediate/Diploma	Plant and machine operators and assemblers	Joint	Graduate	plant and machine operators and assemblers	3072–5119	upper middle class
7	H.K	16	1604324	Middle School Certificate	Skilled workers and shop and market sales workers	Nuclear	Intermediate/Diploma	legislators, senior official or managers	7681–10,240	upper middle class
8	G.G	24	27319	Graduate	Plant and machine operators and assemblers	Nuclear	primary School Certificate	elementary occupation	3072–5119	upper middle class
9	M	27	1620588	Middle School Certificate	Plant and machine operators and assemblers	Nuclear	Middle Schoool Certificate	legislators, senior official or managers	7681–10,240	upper lower class
10	E	25	1622270	High School Certificate	Plant and machine operators and assemblers	Nuclear	primary School Certificate	plant and machine operators and assemblers	1034–3071	upper class
11	H.K	20	1615264	Intermediate/Diploma	Skilled workers and shop and market sales workers	Nuclear	primary School Certificate	plant and machine operators and assemblers	3072–5119	upper middle class
12	H.K	29	1143177	High School Certificate	Plant and machine operators and assemblers	Joint	Graduate	skill worker/ shop and market sales workers	3072–5119	upper lower class
13	S	32	1476944	Graduate	Elementary occupation	Nuclear	primary School Certificate	legislators, senior official or managers	1034–3071	upper middle class
14	P.S	23	599565	Intermediate/Diploma	Skilled agricultural and fishery workers	Nuclear	Graduate	plant and machine operators and assemblers	3072–5119	upper lower class
15	J.K	34	1405857	High School Certificate	Plant and machine operators and assemblers	Joint	Intermediate/Diploma	plant and machine operators and assemblers	≤1033	upper class

SR. NO.	NAME	PHARMACOLOGICAL TREATMENT HISTORY	HDRS PRE	HDRS POST	HDRS FOLLOW UP	HARS PRE	HARS POST	HARS FOLLOW UP	PSQI PRE	PSQI POST	PSQI FOLLOW UP	E-PRE	B-PRE	W-PRE	I-PRE	M-PRE	PCOSQOL-PRE
1	H.K	Femilon, Duonis 30 for &COD, Divaa, Valproate	17	8	6	15	10	5	6	3	3	2	2	2	2	2	10
2	S	ovafresh M	12	5	2	11	3	4	8	2	1	5	7	3	3	5	23
3	G.A	Gyroret Syrup, Pioglitrozone 30	2	0	4	4	0	4	7	4	1	4	3	2	6	3	18
4	J.K	Cyndrella, Seproternon Acetrate	4	4	3	4	2	0	5	8	5	6	6	7	6	4	29
5	T	Norepistrone 30, Ethinyl estradiol + Destgestrol	10	3	2	11	6	5	4	7	3	6	6	6	5	4	27
6	R.K	Metformin	27	9	6	20	9	7	10	7	4	4	4	4	2	6	20
7	H.K	T.normoz once daily x 2m	21	6	9	15	3	9	6	1	5	3	3	3	4	2	15
8	G.G	T.Deviny	17	6	8	13	4	8	2	2	8	5	3	5	7	4	24
9	M	Pioglitazone 30, cyproterone Acetrate	28	9	5	30	12	7	14	4	2	3	5	2	4	4	18
10	E	Metphormin clomiphere	19	5	6	21	7	5	9	4	2	4	2	5	6	4	21
11	H.K	Drospirenone	26	11	11	28	9	8	15	5	9	3	2	1	3	3	12
12	H.K	Decyromethycobalamine, Meta D	32	12	9	37	9	8	17	4	1	2	2	2	5	2	13
13	S	Leuproprein acetrate	19	5	8	19	8	11	16	3	1	4	2	2	3	3	14
14	P.S	Cyproternone Acetrate , Inert faslet	13	10	5	14	12	7	9	8	3	5	5	4	7	3	24
15	J.K	Metformin	9	7	6	5	5	2	1	3	2	6	6	7	7	6	32

SR. NO.	NAME	E-POST	B-POST	W-POST	I-POST	M-POST	PCOSQOL-POST	E-FU	B-FU	W-FU	I-FU	M-FU	PCOSQOL-FU
1	H.K	5	3	4	4	3	19	5	4	5	5	3	22
2	S	6	7	5	3	6	27	7	7	6	5	6	31
3	G.A	5	3	4	7	4	23	6	4	6	7	4	27
4	J.K	6	7	7	7	6	33	5	7	6	6	5	29
5	T	6	7	5	7	5	30	6	7	4	7	6	30
6	R.K	6	5	5	4	7	27	6	6	6	6	7	31
7	H.K	7	6	6	7	5	31	6	5	6	7	4	28
8	G.G	6	4	5	7	4	26	5	5	3	7	6	26
9	M	5	6	4	5	4	24	6	6	6	6	5	29
10	E	6	5	6	7	4	28	6	6	5	3	3	23
11	H.K	6	4	4	6	4	24	6	6	5	7	6	30
12	H.K	5	3	4	7	5	24	7	5	6	7	6	31
13	S	5	5	4	5	6	25	6	7	6	6	6	31
14	P.S	5	6	4	7	5	27	6	7	5	7	6	31
15	J.K	7	7	7	7	7	35	7	7	6	7	6	33

SR. NO.	NAME	AGE	MRD.NO	EDUCATION	OCCUPATION	FAMILY TYPE	EDUCATION OF HEAD OF THE FAMILY	OCCUPATION OF THE HEAD OF THE FAMILY	MONTHLY INCOME OF THE FAMILY	SES
16	J.K	31	1597463	Intermediate/Diploma	Skilled agricultural and fishery workers	Nuclear	Intermediate/Diploma	plant and machine operators and assemblers	1034–3071	upper middle class
17	T.K	18	1621034	Primary school Certifacte	Skilled workers and shop and market sales workers	Nuclear	Professional/Honours	plant and machine operators and assemblers	3072–5119	upper class
18	s	30	1557825	Intermediate/Diploma	Plant and machine operators and assemblers	Joint	primary School Certificate	legislators, senior official or managers	1034–3071	upper class
19	N	34	1144187	Intermediate/Diploma	Craft and related trade workers	Joint	primary School Certificate	legislators, senior official or managers	1034–3071	upper class
20	M	31	1372612	Graduate	Plant and machine operators and assemblers	Nuclear	Graduate	elementary occupation	1034–3071	lower middle class
21	N	29	1641667	High School Certificate	Plant and machine operators and assemblers	Nuclear	Middle Schoool Certificate	plant and machine operators and assemblers	≤1033	upper class
22	T	17	1574566	High School Certificate	Skilled agricultural and fishery workers	Nuclear	High School Certificate	legislators, senior official or managers	≤1033	upper class
23	D	29	1555845	Graduate	Skilled agricultural and fishery workers	Joint	Illiterate	legislators, senior official or managers	≤1033	upper middle class
24	P.P	29	281012	High School Certificate	Plant and machine operators and assemblers	Joint	primary School Certificate	craft and related trade workers	≤1033	upper middle class
25	F.T	33	1283944	Intermediate/Diploma	Plant and machine operators and assemblers	Nuclear	Intermediate/Diploma	plant and machine operators and assemblers	≤1033	lower middle class
26	H.P	28	1651714	Graduate	Skilled agricultural and fishery workers	Nuclear	Intermediate/Diploma	plant and machine operators and assemblers	≤1033	upper middle class
27	N.G	28	1361186	Graduate	Skilled workers and shop and market sales workers	Nuclear	Intermediate/Diploma	craft and related trade workers	≤1033	lower middle class
28	V	19	1638104	High School Certificate	Skilled workers and shop and market sales workers	Nuclear	Middle Schoool Certificate	plant and machine operators and assemblers	≤1033	upper middle class
29	S.K	34	1578705	Intermediate/Diploma	Craft and related trade workers	Nuclear	Middle Schoool Certificate	elementary occupation	≤1033	lower middle class
30	N	19	404099	Intermediate/Diploma	Skilled workers and shop and market sales workers	Nuclear	primary School Certificate	legislators, senior official or managers	≤1033	upper class

SR. NO.	NAME	PHARMACOLOGICAL TREATMENT HISTORY	HDRS PRE	HDRS POST	HDRS FOLLOW UP	HARS PRE	HARS POST	HARS FOLLOW UP	PSQI PRE	PSQI POST	PSQI FOLLOW UP	E-PRE	B-PRE	W-PRE	I-PRE	M-PRE	PCOSQOL-PRE
16	J.K	gyrocret syrup, cryproterone acetrate , inert tab	21	17	6	22	19	11	9	9	9	4	4	2	2	4	16
17	T.K	Drospirenone, Doxycyclin 100	26	14	7	30	11	4	13	9	3	4	7	3	6	3	23
18	s	Ovafresh M 50	14	6	5	13	5	7	4	1	2	4	5	2	2	3	16
19	N	Metformin	13	3	9	19	7	6	8	1	2	5	5	7	7	4	28
20	M	cyndrella, Cuprotenone acetrate	5	5	4	7	3	5	1	1	4	5	6	6	6	4	27
21	N	Ethinyl estradiol+desogestrol, Metformin 2	7	4	9	9	6	12	1	3	3	4	4	7	6	5	26
22	T	sotret, azee	21	6	6	23	8	8	14	5	5	4	6	7	7	4	28
23	D	shatvali , ashvagandha, nariurja,susten, lotoval 2.5mg, myonews	14	8	6	13	7	6	7	2	6	2	3	4	3	2	14
24	P.P	bonecard, devil	16	11	9	16	12	10	13	7	5	5	7	4	7	5	28
25	F.T	Drospirenone 30, Pigolitazone 30	3	7	5	7	4	2	6	9	5	4	4	4	6	2	20
26	H.P	Gyrocret Syrup, sotret 20	18	13	6	17	11	9	10	4	1	3	3	3	5	5	19
27	N.G	Cyndrella, Seproternon Acetrate	11	3	4	15	8	8	2	0	3	5	7	3	6	6	27
28	V	Gokshura ayurvedic	12	21	11	14	23	6	4	15	6	5	6	2	6	4	23
29	S.K	Vaniqua cream	23	7	6	17	8	5	9	2	2	5	2	4	2	4	17
30	N	Ethinyl estradiol+desogestrol	14	3	4	10	5	4	11	2	1	3	5	5	6	5	24

SR. NO.	NAME	E-POST	B-POST	W-POST	I-POST	M-POST	PCOSQOL-POST	E-FU	B-FU	W-FU	I-FU	M-FU	PCOSQOL-FU
16	J.K	5	5	4	2	4	20	4	6	4	2	4	20
17	T.K	4	7	4	6	5	26	5	7	6	7	6	31
18	s	5	5	5	3	6	24	6	5	5	5	7	28
19	N	6	6	6	6	6	30	6	7	6	5	7	31
20	M	6	6	5	4	5	26	7	6	6	4	4	27
21	N	6	6	7	7	6	32	6	5	5	7	6	29
22	T	6	6	7	7	4	30	6	6	7	7	4	30
23	D	5	5	5	3	3	21	6	6	6	4	4	26
24	P.P	6	7	4	7	5	29	6	5	3	6	5	25
25	F.T	5	5	4	7	4	25	6	7	6	7	6	32
26	H.P	5	4	3	5	6	23	6	5	4	7	6	28
27	N.G	6	7	5	7	6	31	7	7	5	7	7	33
28	V	4	7	3	7	5	26	6	7	5	4	7	29
29	S.K	6	4	6	6	5	27	5	4	6	4	4	23
30	N	6	6	6	4	6	28	7	6	6	7	7	33

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No. BFUHS/2K24p-TIU /8007 Date 22/4/24

The Principal,
Dayanand Medical College ,
Ludhiana.

Subject: Approval of Plan of Thesis.

This is to inform you that the Faculty of Medical Sciences in its meeting held on 22.01.2024 has approved the plan of thesis of **Ms. Meitrai Mehta,** a student of your college for **M.Phil. (Clinical Psychology)** along with the names of Supervisor/Co-Supervisor as under :-

Topic Plan of Thesis
Effect of cbt on psychological morbidity, quality of life and sleep disturbance in women with polycystic ovarian syndrome, pre and post study .

Supervisor
Ms Palak Upadhyay,
Asst. Professor
Dept. of Clinical Psychology

Co-Supervisor
Dr.Bholeshwar Prasad Mishra
Prof. & Head
Dept. of Clinical Psychology
Dr. Pooja Tandon
Professor
Dept. of Obstetric & Gynaecology

The student has to submit the three copies of thesis (along with PDF format) , to the Controller of Examinations, BFUHS, Faridkot, at least six months before the commencement of theory examination, if he/she is otherwise eligible to take the examination. He /She must directed to attach a photocopy of this letter with the forwarding letter while submitting thesis to the University along with the letter of approval of University for change of supervisor/Co-Supervisor, change of topic.(if any).

Controller of Examinations

Note :
1. *If any discrepancy found regarding topic of thesis or Supervisor/Co-Supervisor, inform undersigned within one month after issue of this letter.*

EFFECT OF CBT ON PSYCHOLOGICAL MORBIDITY, QUALITY OF LIFE AND SLEEP DISTURBANCE IN WOMEN WITH POLYCYSTIC OVARIAN SYNDROME, PRE AND POST STUDY

DISSERTATION PROPOSAL

FOR APPROVAL OF SUBJECT OF DISSERTATION TO BE SUBMITTED

IN PARTIAL FULFILMENT OF THE REQUIREMENTS

FOR THE DEGREE OF

M. PHIL

IN

CLINICAL PSYCHOLOGY

OF THE

BABA FARID UNIVERSITY OF HEALTH SCIENCES

FARIDKOT

MARCH, 2023 **MS. MEITRAI MEHTA**

DEPARTMENT OF CLINICAL PSYCHOLOGY
DAYANAND MEDICAL COLLEGE AND HOSPITAL
LUDHIANA

ABSTRACT OF PLAN OF DISSERTATION

Title	EFFECT OF CBT ON PSYCHOLOGICAL MORBIDITY, QUALITY OF LIFE AND SLEEP DISTURBANCE IN WOMEN WITH POLYCYSTIC OVARIAN SYNDROME, PRE AND POST STUDY
For the degree of	M. Phil Clinical Psychology
Name of the candidate	Ms. Meitrai Mehta
Supervisor	Palak Upadhyay, Assistant Professor, Department of Clinical Psychology, DMCH, Ludhiana
Co-supervisor	Dr. Bholeshwar Prasad Mishra, Professor & Head, Department of Clinical Psychology, DMCH, Ludhiana. Dr. Pooja Tandon, Professor , Department of Obstetrics & Gyanaecology, DMCH, Ludhiana
Institution	Dayanand Medical College & Hospital, Ludhiana
University	Baba Farid University of Health Sciences, Faridkot

Introduction: Polycystic ovary syndrome (PCOS) is the most common multifaceted endocrine disorder with a spectrum of manifestations affecting women presenting with clinical, hormonal and psychological manifestation which significantly impact the quality of life (QoL) of women further contributing to psychological morbidity and sleep disturbances. CBT has been used in the treatment of aforementioned variables. Objectives of the study will be to evaluate the effect of CBT on QoL, psychiatric morbidity and sleep disturbances in women with PCOS.

Aim of Study: 1) To study the pre and post effect of CBT on psychological morbidity in women with PCOS. 2) To study the pre and post effect of CBT on Quality of Life in women with PCOS. 3) To study the pre and post effect of Sleep disturbances in women with PCOS

Materials & methods: Study will be conducted on 30 patients diagnosed with PCOS, admitted in Obstetrics and Gynaecology ward or visiting Obstetrics and gynaecology OPD at DMC&H. They will be required to fill HDRS, HARS, PSQI & POCS-QOL pre and post intervention.

Clinical Significance: The study will contribute to efficacious treatment of PCOS using cognitive behavioural approaches by working on the psychological aspects leading to the development of PCOS.

Keywords: Polycystic ovary syndrome, cognitive behavioural therapy, intervention, depression, anxiety, quality of life, sleep disturbance, insomnia, psychological morbidity

(Signature) Candidate	(Signature) Co-supervisor	(Signature) Co-supervisor	(Signature) Supervisor	(Signature) Principal

CERTIFICATE OF FACILITIES AVAILABLE

This is to certify that the facilities for work on the subject of dissertation titled **"EFFECT OF CBT ON PSYCHOLOGICAL MORBIDITY, QUALITY OF LIFE AND SLEEP DISTURBANCE IN WOMEN WITH POLYCYSTIC OVARIAN SYNDROME, PRE AND POST STUDY"** exist in the Department of Clinical Psychology, DMC&H, Ludhiana and will be provided to the candidate. We will see that the data being included in the dissertation is genuine and is collected by the candidate herself under our supervision and guidance.

Supervisor

Palak Upadhyay
Assistant Professor
Department of Clinical Psychology
DMCH, Ludhiana

Co-Supervisors

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Head of the Department

Dr. Bholeshwar Prasad Mishra
Professor & Head
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Place: Ludhiana

Date: _____

APPROVAL PROFORMA
BY RESEARCH & ETHICAL COMMITTEE
DAYANAND MEDICAL COLLEGE & HOSPITAL, LUDHIANA

Name of candidate	Ms. Meitrai Mehta
Department	Clinical Psychology
Topic of Dissertation	EFFECT OF CBT ON PSYCHOLOGICAL MORBIDITY, QUALITY OF LIFE AND SLEEP DISTURBANCE IN WOMEN WITH POLYCYSTIC OVARIAN SYNDROME, PRE AND POST STUDY
Likely date of appearing in PG examination	May/June 2024
Date of enrollment	16.08.2022
Name of Head of Department	Dr. Bholeshwar Prasad Mishra
1) Supervisor **2) Co-Supervisor(s)**	Palak Upadhyay Dr. Bholeshwar Prasad Mishra Dr. Pooja Tandon
Signature of Members of Research Committee with Stamp	**Signature of Members of Ethics Committee with Stamp**
Dr. Harpreet Kaur (Professor & Head, Pathology)	Adv. Ankur Ghai (Legal Expert)
Dr. Jaspal Singh (Professor & Head, Surgery)	Dr. Suvir Singh (Associate Professor, Haematology)
Dr. Dinesh Gupta (Professor & Head, Medicine)	Dr. Ramit Mahajan (Professor, Gastroenterology)
Dr. Sandeep Kaushal (Dean Academics & Professor & Head, Pharmacology)	Dr. Ashvind Bawa (Professor, Surgery)
Dr. Gurpreet S Wander (Vice Principal, Professor, Cardiology)	Dr. Sandeep Kaushal (Professor & Head, Pharmacology)
	Dr. Gurpreet S Wander (Vice Principal, Professor, Cardiology)
	Dr. Rajesh Mahajan (Secretary, Ethics Committee Professor, Medicine)

Approved: Yes ~~/ No~~

Dr. Sandeep Puri
Chairperson
Research Committee
Chairperson
Research Committee

Approved: Yes / ~~No~~

Prof. Arvind Malhotra
Chairperson
Ethics Committee
Chairperson
Ethics Committee

BABA FARID UNIVERSITY OF HEALTH SCIENCES, FARIDKOT

PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION

1	NAME OF THE CANDIDATE AND ADDRESS	MS. MEITRAI MEHTA 22/342, PANERIYON KI MADRI, BADA MANDIR, HOLICHOWK, UDAIPUR (RAJASTHAN)
2	NAME OF THE INSTITUTE	DAYANAND MEDICAL COLLEGE AND HOSPITAL, LUDHIANA
3	COURSE OF STUDY AND SUBJECT	M.PHIL CLINICAL PSYCHOLOGY
4	DATE OF ADMISSION OF COURSE	08.08.2022
5	TITLE OF THE TOPIC	EFFECT OF CBT ON PSYCHOLOGICAL MORBIDITY, QUALITY OF LIFE AND SLEEP DISTURBANCE IN WOMEN WITH POLYCYSTIC OVARIAN SYNDROME, PRE AND POST STUDY

6. BRIEF RESUME OF THE INTENDED WORK

6.1 NEED FOR THE STUDY

Polycystic ovary syndrome (PCOS) is considered to be one of the most common multifaceted endocrine disorder with a spectrum of manifestations predominantly affecting women of reproductive age.

The global prevalence of PCOS is estimated between 4% and 20% (Deswal, et al. 2020).[1] Prevalence of PCOS in India ranges from 3.7% to 22.5% depending on the population studied and the criteria used for diagnosis (Bulsara et al. 2021).[2] The National Institutes of Health (NIH) criteria require menstrual irregularity and evidence of androgen excess. The Rotterdam guideline accepts any two out of three criteria consisting of menstrual irregularity, androgen excess, and polycystic ovary morphology (PCOM) on ultrasound. The Androgen Excess and PCOS Society (AE-PCOS) recommends diagnosis in the presence of hyperandrogenism with either menstrual irregularity or PCOM. In December 2012, the NIH's Evidence-based Methodology Workshop on Polycystic Ovary Syndrome recommended upholding the broad, inclusionary Rotterdam criteria while specifically identifying the distinct PCOS phenotype (Kamboj and Bonny 2017)[3], however, hyperandrogenism was not considered imperative for the diagnosis. (Karjula, 2021).[4]

Clinical disorders associated with the PCOS include irregular menstrual cycles, amenorrhea, hirsutism, acne, alopecia, and infertility (Babapour et al., 2019).[5] In addition to the common somatic comorbidities of the syndrome, there is emerging evidence showing higher risk for psychological distress and an increased prevalence of more severe psychiatric diseases, e.g., schizophrenia, in females with PCOS. Existing literature has indicated that the syndrome is also linked with a higher risk for depression, anxiety, and disordered eating (Cesta et al., 2016)[6] along with psychiatric and psychological morbidity where psychological morbidity refers to a departure from a state of

psychological wellbeing resulting from disease, illness, injury, or sickness (Cook, 2018).[7] Given that women with PCOS often present to health care providers early in their reproductive years, there is an opportunity to modify these risk factors (Cooney et al., 2018).[8] Moreover, the syndrome remains underdiagnosed, resulting in insufficient support and inadequate treatment outcomes (Teede et al., 2017).[9]

International evidence-based guidelines for PCOS recommend depression and anxiety screening and lifestyle modification as the first line of treatment to improve and manage the patient's quality of life. Despite attentive scrutiny in the assessment of impact of a condition and its treatment on QoL, little consensus has been reached on the definition of QoL and a "remarkably wide range of meanings is implied by the choice of instruments used to measure quality of life" (Bradley, 1996)[10] In the absence of a universally agreed and specific definition of QoL, variety of patient-reported outcomes have been considered as indicative of QoL. There is, however, some agreement regarding the consideration of QoL as a multidimensional notion involving the assessment of physical, psychological, and social aspects of life which is subjective, dynamic and unique to the individual concerned in relation to the inconsistency between their perceived and attained goals. Given that PCOS presents with a variety of adverse, highly burdening clinical manifestations and comorbidities, the health-related quality of life in affected women calls for more attention.

Since PCOS is characterized by metabolic disturbances, and as the endocrine system has an important role in governing the sleep–wake cycle, it is likely that PCOS interferes with arousal and sleep resulting in sleep disturbances. Some of the common sleep disturbance conditions which are prevalent include sleep apneas, insomnia, delayed sleep phase, daytime sleepiness, sleepwalking, nightmares, and restless leg movement. (Gaultney JF, 2011).[11] Evidence suggests that women around an age of 30s with PCOS have double sleep

disturbance as compared to their normal counterparts, but the reason for so was not clear. Specifically, chronic insomnia is associated with symptoms such as severe sleepiness, fatigue, memory impairment, and impaired attention and concentration that adversely affect social functioning and quality of life (Buysse DJ, 2007)[12]

Cognitive behavioral therapy (CBT) is a type of psychotherapy that modifies cognitive patterns and provides behavioral restructuring to alter psychological symptoms and behaviors. CBT has been successful in the treatment of various illnesses including obesity, depression, anxiety, insomnia, and other chronic disorders (Citrome et al., 2011)[13] International evidence-based guidelines for PCOS recommend CBT to help patients adhere to and maintain healthy lifestyles and improve health outcomes (Teede et al., 2018) .

CBT is recommended as a first-line treatment for depression (Qaseem, 2016). It is a psychotherapy that focuses on changing dysfunctional thoughts that lead to negative mood states and maladaptive behaviors (Gelenberg et al. 2010).[14] It has been posited that CBT combined with practical medical science techniques can assist women with the PCOS in overcoming barriers to coping with lifestyle changes and in recovering from or preventing the progression of their disease (Correa. J.B., 2015).[15] Studies have implicated the role of insomnia in development and persistence of dysfunctional beliefs about sleep and poor sleep hygiene. CBT for Insomnia is found to improve sleep disturbances by replacing dysfunctional beliefs and attitudes toward sleep with more functional concepts. Despite increasing interest and research, it is still unclear how the psychological and psychiatric health and HRQoL of women with PCOS are affected through aging up to menopause. There is a paucity of literature from India addressing the effects of CBT on relationship between Psychological morbidity, Quality of life and sleep disturbances in women with PCOS. Therefore, overall aim of the study is to compare the feasibility and preliminary efficacy of an intervention which combine CBT and pharmacological treatment on

the treatment of aforementioned variables in women with PCOS. Thus, this study aims to study the above aspects namely relationship between Psychological morbidity, quality of life, psychological fatigue and sleep disturbance in women with PCOS in India.

6.2 REVIEW OF LITERATURE

Polycystic ovary syndrome (PCOS) is a complex endocrine disorder affecting the reproductive, metabolic and psychological health of women. Studies indicate that infertility, metabolic, cosmetic problems, mood disturbances including symptoms of depression, decreased sexual satisfaction, problems with feminine identity and decreased quality of life occur more frequently among women with PCOS. The following international bodies have established diagnostic criteria for PCOS: National Institutes of Health/National Institute of Child Health and Human Disease (Zawadski JK and Dunaif A. 1992)[16], the European Society for Human Reproduction and Embryology/American Society for Reproductive Medicine or the "Rotterdam Criteria;" and the Androgen Excess and PCOS Society (Carmina et al., 2016).[17] For the purpose of this study, the Rotterdam criteria has been applied for patient's selection. According to these criteria, presence of any two (1. oligo/anovulation, 2. hyperandrogenism, and 3. polycystic ovaries on ultrasound) is necessary for the diagnosis of poly ovary cystic disease (POCD).

Barth et al. (1993) conducted a study on "Psychological morbidity in women referred for treatment of hirsutism" to determine the prevalence of psychological morbidity and to identify factors associated with psychiatric symptoms. Sixty-nine pre-menopausal hirsute women participated in the study. General Health Questionnaire (GHQ-28), Profile of Mood States (POMS), Eysenck Personality Questionnaire (EPQ-R) and Rosenberg's Self-Esteem Inventory were administered. The result of the study indicated that hirsutism was found to be positively correlated with levels of psychiatric disturbance. It also suggested that higher levels of neuroticism and introversion was found to be significantly correlated with avoidance of social situations.

Lobo and Carmina (1999) conducted a study on "Polycystic Ovary Syndrome: Arguably the Most Common Endocrinopathy Is Associated with Significant Morbidity in Women". The study identified PCOS to be

a common disorder of women associated with significant reproductive and non reproductive morbidity. The result of the study suggests significant correlation and increased prevalence of reactive depression and minor psychological abnormalities with hirsutism.

A study was conducted by Stuckey et al. (2007)[18] on “Quality of life and psychological morbidity in women with polycystic ovary syndrome: body mass index, age and the provision of patient information are significant modifiers”. A total of 203 women aged 15–65 years participated in the study. GHQ-28 and PCOSQ were administered. The study identified an increased prevalence of psychological morbidity and impaired QoL. Significant correlation between perception of inadequate information with poorer QoL scores was found to be present in women with PCOS.

“Cognitive behavioural therapy for physical and emotional disturbances in adolescents with polycystic ovary syndrome: A Pilot Study” was the subject of a study by Rofey et al. (2008).[19] A total of 12 adolescents with PCOS, obesity, and depression underwent an open trial where eight weekly sessions and three family-based sessions of CBT enhanced by lifestyle goals, physical illness narrative and family psychoeducation was provided. Results of the study indicated significant reduction in weight across and the depressive symptoms. A manual-based CBT approach to treat depression in adolescents with PCOS and obesity was found to be promising as indicated by the results of the study.

M. Pilar Martínez et al. (2013)[20] conducted a study to examine the efficacy of a cognitive-behavioral therapy for insomnia (CBT-I) versus a sleep hygiene (SH) education program at improving sleep and other clinical manifestations in fibromyalgia. A total of 59 fibromyalgia women with insomnia participated in the study. The findings revealed significant improvement in sleep variables, fatigue, daily functioning, pain catastrophizing, anxiety and depression when treated with CBT for Insomnia. Significant improvement in subjective sleep quality was

reported by the Sleep hygiene group. The findings highlighted the usefulness of CBT- Insomnia in the multidisciplinary management of fibromyalgia.

A study was undertaken by Espie et al., (2018)[21] on “Effect of Digital Cognitive Behavioral Therapy for Insomnia on Health, Psychological Well-being, and Sleep-Related Quality of Life: A Randomized Clinical Trial” to investigate the effect of digital CBT for insomnia on functional health, psychological well-being, and sleep-related quality of life and to determine whether a reduction in insomnia symptoms was a mediating factor. A total of 1711 participants participated in the study. Digital CBT and sleep hygiene education were provided for 12 weeks. The results of the study indicated that the use of digital CBT was effective in improving functional health, psychological well-being, and sleep-related quality of life. The study highlighted that digital CBT improves both daytime and nighttime aspects of insomnia, strengthening existing recommendations of CBT as the treatment of choice for insomnia.

Babapaur et al., (2018) conducted a study to determine the effects of cognitive-behavioral therapy (CBT) on the quality of life and psychological fatigue in women with the PCOS. A total of 74 women aged between 18 and 35 years from the Iranian city of Saqqez participated in the study. The Polycystic Ovary Syndrome Health-Related Quality of Life Questionnaire (PCOSQ) and the Fatigue Impact Scale (FIS) were completed. The results showed that CBT was able to reduce fatigue and improve quality of life in women with the PCOS.

Cooney et al., (2018) conducted a study to examine “Cognitive-behavioral therapy improves weight loss and quality of life in women with polycystic ovary syndrome: a pilot randomized clinical trial”. A total of 7 women participated in the study. Weekly CBT for 8 weeks and weekly Life style intervention (LS) for 16 weeks was provided. Results of the study showed that the weekly CBT along with LS resulted in significant weight loss and improved quality of life in overweight women with PCOS and depressive symptoms as compared with LS alone.

A research study was conducted by Shilpa. S and Nithya. R (2020)[22] to examine the effectiveness of Benson Relaxation and Supportive therapy on perceived loneliness and quality of life among PCOS women. A total of 30 women aged between 25-45 years from Kerala participated in the study. Perceived Loneliness Scale and SF-36 were used. Result of the study showed that Supportive and Relaxation therapy were found to be effective in reducing perceived loneliness and enhancement of quality of life among PCOS women.

Jiskoot et al.,(2020)[23] conducted a study on "Long-term effects of a three-component lifestyle intervention on emotional well-being in women with Polycystic Ovary Syndrome (PCOS): A secondary analysis of a randomized controlled trial" to examine the effect of CBT lifestyle (LS) sessions combined with a healthy diet and physical therapy with or without additional feedback through Short Message Service (SMS) compared to care as usual (CAU). A total of 55 women with PCOS participated in the study. The results of the study indicated that the LS programme resulted in significant reduction in depression as compared to CAU. A three-component lifestyle intervention programme with or without additional SMS resulted in significant improvements in depression and self-esteem compared to CAU. The findings suggested that the lifestyle treatment independent of weight loss resulted in reduction in depression and body-image issues, but both lifestyle treatment and weight loss contributed to improvement of self-esteem. A three-component lifestyle intervention based on CBT was proven successful in improving mood in women with PCOS who were overweight or obese and were attempting to become pregnant.

"Relationship between anxiety, depression and quality of life in medical student with polycystic ovary syndrome" was undertaken as a research study by Sharma (2021)[24] 70 medical students from Udaipur, Rajasthan participated in the study. Hamilton depression rating scale for depression, Hamilton anxiety rating scale for anxiety, and 36-item short form survey for QoL were administered. Results of the study revealed that the students with PCOS and psychological morbidity

(anxiety and depressive symptoms) had a lower QoL compared to their counterparts without psychological morbidity.

Almis et al. (2021)[25] conducted a study on “Self-Concept, Depression, and Anxiety Levels of Adolescents with Polycystic Ovary Syndrome” to explore the level and severity of issues related to self-concept, depression, and anxiety in adolescents with PCOS. A total of 53 patients with PCOS and 161 healthy adolescents participated in the study. The findings of the study indicated a positive correlation between self-concept, anxiety, and depressive symptoms in adolescents with PCOS.

Karjula (2021) conducted a study on “Long-term consequences of polycystic ovary syndrome on mental health and health related quality of life”. The study population comprised of 5889 females from Northern Finland. The findings of the study identified PCOS to be an independent risk factor for psychological distress up to a late reproductive age. PCOS was found to be positively correlated with an increased risk for psychosis and long-term decrease in health related quality of life.

Urgulru and Kokack (2022)[26] conducted a study to determine depression symptoms and quality of life in women PCOS. A total of 131 women participated in the study. PCOS Quality of Life Questionnaire, and Beck Depression Inventory were administered. It was found that perceived of income as sufficient and having an employment, negatively correlated with depression while it correlated positively with hirsutism and acne. The quality of life was found to be negatively correlated with depressive symptoms.

Kausar et al., (2022)[27] conducted a study on “Increased Risk of Infertility, Marital Maladjustment and Psychological Morbidity in PCOS Patients of Southern Punjab, Pakistan”. A total of 354 women participated in the study. The findings revealed that anxiety, depression, sleep apnea, eating disorders, marital maladjustment, poor quality of life and migraine was significantly prevalent in women with

PCOS as compared to controls. A significant correlation between infertility and psychotic symptoms along with comorbidity between psychological morbidity and infertility was found to be present in PCOS female.

Tang et al., (2022)[28] conducted a meta-analytical study to evaluate the effectiveness of CBT in improvement of weight loss, anxiety, depression, life quality, compliance, and pregnancy outcomes in patients with PCOS. Results of the study indicated that CBT resulted in the alleviation of anxiety, improvement of quality of life in hirsutism, increased compliance and rate of pregnancy in patients with PCOS.

Together, these findings suggest that psychological morbidity, sleep disturbances and reduction in quality of life in women with PCOS may alter their functioning. The literature collected indicate the role of CBT in dealing with aforementioned variables preventing the progression of PCOS.

6.3 AIMS AND OBJECTIVES OF THE STUDY

1. To study the pre and post effect of CBT on psychological morbidity in women with PCOS.
2. To study the pre and post effect of CBT on Quality of Life in women with PCOS.
3. To study the pre and post effect of Sleep disturbances in women with PCOS.

7. MATERIALS AND METHODS

7.1 SOURCE OF DATA

Study will be conducted on 30 patients diagnosed with PCOS by the gynaecologist, admitted in Gynaecology ward or visiting gynaecology OPD at Dayanand Medical College and Hospital, Ludhiana.

7.2 METHOD OF COLLECTION OF DATA

Design: Pre- Post Intervention Design.

Sample size: 30 patients diagnosed with PCOS.

Sample design: Purposive sampling design will be used. The respondents who meet the inclusion criteria will be selected for the study.

INCLUSION CRITERIA

- Fulfilment of Rotterdam's criteria (2003): 2 out of 3 diagnostic criteria of oligo/anovulation, clinical or biochemical hyperandrogenism, and a diagnosis of polycystic ovaries based on ultrasound results (on treatment)
- Female participants belonging to an age group between 18 to 35 years willing to give informed consent.

EXCLUSION CRITERIA

- Presence of Hypothyroidism (untreated).
- Presence of Hyperprolactinemia (untreated).
- Pregnant females.
- Presence of any other medical comorbidity will be excluded.
- History of substance use disorder.
- Linguistic or cognitive difficulties preventing reliable completion of the questionnaire.
- History of Intellectual disability.
- Presence of any major psychiatric illness.

DESCRIPTION OF THE TOOLS:

i. **Socio- demographic Proforma (Kuppuswamy, 2019); Informed consent form.**

A semi structured pro-forma was designed for the present study in order to collect detailed clinical history of each participant including information related to the following areas:

- Socio-demographic details including age, gender, MRD number, occupation, education, income, marital status.
- Treatment modality
- Scores of all the test

ii. **Hamilton depression rating scale (HDRS):** It is a multiple item questionnaire is used to rate the severity of depressive symptoms. Eight items are rated on a 5-point scale (0=absent; 1=doubtful or mild; 2=mild to moderate; 3=moderate to severe; 4=very severe), while the remaining 9 items are rated on a 3-point scale (0=absent; 1=doubtful or mild; 2=clearly present). The theoretical score range of the scale is from 0 to 52. A score of 0–7 is generally accepted to be within the normal range (or the patient is in the clinical remission phase), while a score of 20 or higher indicating at least moderate severity of the depression. (Hamilton, 1960).

iii. **Hamilton anxiety rating scale (HARS):** The scale consists of 14 items, each defined by a series of symptoms, and measures both psychic anxiety (mental agitation and psychological distress) and somatic anxiety. Each item is scored on a scale of 0 (not present) to 4 (severe), with a total score range of 0–56, where where <17 indicates mild severity, 18–24 mild to moderate severity and 25–30 moderate to severe. (Hamilton, 1959). Internal consistency of the test was found to be 0.77 to 0.92.

iv. **Polycystic Ovary Syndrome Questionnaire (PCOSQ)**: This 26-item questionnaire, developed by Cronin et al, measures quality of life among respondents in the following domains: emotional (items 2, 4, 6, 11, 14, 17, 18 and 20), hirsutism (items 1, 9, 15, 16 and 26), weight (items 3, 10, 12, 22 and 24), infertility (items 5, 13, 23 and 25), and irregular menstruation (items 7, 8, 9 and 21). Each item is given a score according to a seven-point Likert scale, with a score of 7 showing the best performance and a score of 1 showing the weakest performance. Thus, the range of score for the emotional domain is between 8 and 56 points, for the hirsutism and weight domains between 5 and 35 points, and for the infertility and menstrual domains between 4 and 28 points. The total score in each domain is the score of that domain divided by the total number of the items in that domain. Higher scores indicate better function. Cronbach's α fluctuated between 0.70 and 0.85. (Wang, 2022).

v. **Pittsburgh Sleep Quality Index (PSQI)**: PSQI questionnaire consists of 19 questionnaires/items and 7 component scores, each of which has a range of 0–3 points, 0 indicating no difficulty, whereas 3 indicates severe difficulty. The seven components are sleep duration, disturbance, latency, daytime dysfunction, efficiency, quality, and medication. All the seven-component score was added to yield one global score which ranges from 0 to 21 points. A score ≤5 indicates good sleep, and on the other hand, a score >5 indicates poor seep. In each domain, the score ranges from 0 to 3.

PROCEDURE

Baseline assessment- The patient will first undergo informed consent process, in which the necessary information would be provided to enable the participant to make an informed decision. The participants who meet the inclusion criteria and those willing to give consent will be included in the study. The Socio demographic proforma (Kuppuswamy, 2019) containing the basic information about the patient will be filled.

Further, the participants will be assessed on Hamilton depression rating scale (HDRS), Hamilton anxiety rating scale (HARS), Polycystic Ovarian Syndrome- Quality of Life scale (PCOS-QoL) and Pittsburgh Sleep Quality Index (PSQI) in baseline assessment prior to intervention.

After the assessment, each participant will undergo 12 weekly sessions of CBT of 70 minutes each session.

Patients will be re-evaluated on baseline assessment post intervention.

Scores will be compared and analysed using appropriate statistical analysis.

Table 1. session plan (adapted by Rofey, 2000 and Abdollahi, 2019)

S.NO	SESSION	AREA
1	Baseline appointment	Reviewing history, Baseline assessments
2	Session 1	Explaining the anatomy and physiology of the reproductive system, defining the ovaries and the mechanism of their function. Information about the relationship between sleep and PCOS, basic notions about sleep, and sleep hygiene education. Introduction and maintenance of sleep diary

		along with Thought diary. Diaphragmatic breathing.
3	Session 2	Follow up on the previous session's assignment in consecutive sessions. ABC Model; Identifying situations, behaviors, emotions that leads to distress. Maintenance of thought diary. Practice of relaxation techniques.
4	Session 3	Follow up on the previous session's assignment in consecutive sessions. Identification of Cognitive distortion. Self affirmative statements were introduced. Maintenance of thought diary. Sleep hygiene would be emphasized along with Jacobson Progressive Muscle Relaxation (JPMR).
5	Session 4	Information about the role of Lifestyle modification in PCOS was introduced. Behavioral activation. Maintenance of thought diary.
6	Session 5	Follow up on the previous session's assignment in consecutive sessions. Modifying negative cognitive distortions and attributions concerning health aspects, emotions, and physical self. Identification of negative self talk along with

		generation of empowering alternatives. Jacobson Progressive Muscle Relaxation (JPMR).
7	Session 6	Follow up on the previous session's assignment in consecutive sessions. Changing negative automatic thoughts about sleep disturbance. Behavioral experiments was focused upon. Reassessment of lifestyle goals. Jacobson Progressive Muscle Relaxation (JPMR).
8	Session 7	Problem solving: Pros & Cons of behavior. Stimulus control and Sleep restriction was introduced. Practice of relaxation techniques.
9	Session 8	Follow up on the previous session's assignment in consecutive sessions. Increment in physical exertion. Problem solving: Identification of the problem, Generation of potential solution, Evaluation of alternatives. Practice of relaxation techniques.
10	Session 9	Follow up on the previous session's assignment in consecutive sessions. Problem solving: Implementation of the solution, evaluating outcome. Practice of relaxation techniques.

11	Session 10	Follow up on the previous session's assignment in consecutive sessions. Review Behavioral experiment and discuss the barriers experienced. Self- management. Building autonomy. Practice of relaxation techniques.
12.	Session 11	Maintenance of achievements and prevention of relapses. Practice of relaxation techniques.
13.	Session 12	Follow up and therapy termination. Post intervention assessment
14.	Follow up	

OUTCOME

In this study, it will be observed that patients diagnosed with PCOS experience low QoL, psychological morbidity and sleep disturbance. Use of CBT with patients with PCOS will yield positive results in terms of improving their QoL, and reducing their psychological morbidity and sleep disturbances. The findings of the study would add to enrich the existing fund of knowledge. This will have direct implications for therapeutic planning and relapse prevention while treating patients with PCOS.

STATISTICAL ANALYSIS

Data will be described in terms of range; mean ±standard deviation (± SD), median, frequencies (number of cases) and relative frequencies (percentages) as appropriate. Comparison of quantitative variables between the study groups will be done using Paired t-test and Wilcoxon rank test for independent samples for parametric and non-parametric data respectively. All statistical calculations will be done using (Statistical Package for the Social Science) SPSS 21version (SPSS Inc., Chicago, IL, USA) statistical program for Microsoft Windows.

7.3 DOES THE STUDY REQUIRE ANY INVESTIGATIONS OR INTERVENTIONS TO BE CONDUCTED ON PATIENTS OR OTHER HUMANS OR ANIMALS? IF SO, PLEASE DESCRIBE BRIEFLY.

No

7.4 HAS ETHICAL CLEARENCE BEEN OBTAINED FROM YOUR INSTITUTION IN CASE OF 7.3?

Yes, Attached herewith

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SOCIO-DEMOGRAPHIC PROFORMA

S.NO: - **Date:**

1. NAME:

2. AGE:

3. MRD.NO: -

4. Education-

a) Illiterate b) Up to Matric**.** c) 10th d) 12th e) Graduate

f) Post graduate

5. Occupation-

a) Farmer/Clerical/Shopkeeper b) Semi-skilled/skilled worker c) Unemployed d) Other

e) Professional f) Student

6. Address- a) Urban b) Rural

7. Contact no.-

8. Family Type- a) Nuclear b) Joint

9. Education of the Head of the family

Profession or honors

Graduate

Intermediate or diploma

High school certificate

Middle school certificate

Primary school certificate

Illiterate

10. Occupation of the head

Legislators, senior officials, and managers

Professionals

Technicians and associate professionals

Clerks

Skilled workers and shop and market sales workers

Skilled agricultural and fishery workers

Craft and related trade workers

Plant and machine operators and assemblers

Elementary occupation

Unemployed

11. Monthly income of the family

- ≥20,482
- 10,241–20,481
- 7681–10,240
- 5120–7680
- 3072–5119
- 1034–3071
- ≤1033

12. Socio economic status

Upper

Upper middle

Lower middle

Upper lower

Lower

13. Time since diagnosis

14. Pharmacological treatment history

15. SCALES:

Hamilton depression rating scale (HDRS)

Hamilton anxiety rating scale (HARS)

Pittsburgh Sleep Quality Index (PSQI)	
Domain	Component Score
Sleep duration	
Sleep disturbance	
Latency	
Daytime sleep	
Sleep Dysfunction	
Sleep quality	
Medication	
Global score	

Polycystic Ovary Syndrome Questionnaire (PCOSQ)	
Domain	Score
Emotional domain	
Hirsutism	
Weight	
Infertility	
Irregular menstruation	
Overall	

16. PSYCHOTHERAPEUTIC INTERVENTION

	HDRS	HARS	PSQI	POCS-QOL					Total
				E	B	W	I	M	
Pre intervention scores									
Session 1									
Session 2									
Session 3									
Session 4									
Session 5									
Session 6									
Session 7									
Session 8									
Session 9									
Session 10									
Session 11									
Session 12									
Post intervention scores									
Follow up Scores									

Hamilton Depression Rating Scale (HDRS)

Reference: **Hamilton M. A rating scale for depression. J Neurol Neurosurg Psychiatry 1960; 23:56-62**

Rating Clinician-rated

Administration time 20–30 minutes

Main purpose To assess severity of, and change in, depressive symptoms

Population Adults

Commentary

The HDRS (also known as the Ham-D) is the most widely used clinician-administered depression assessment scale. The original version contains 17 items ($HDRS_{17}$) pertaining to symptoms of depression experienced over the past week. Although the scale was designed for completion after an unstructured clinical interview, there are now semi-structured interview guides available. The HDRS was originally developed for hospital inpatients, thus the emphasis on melancholic and physical symptoms of depression. A later 21-item version ($HDRS_{21}$) included 4 items intended to subtype the depression, but which are sometimes, incorrectly, used to rate severity. A limitation of the HDRS is that atypical symptoms of depression (e.g., hypersomnia, hyperphagia) are not assessed (see SIGH-SAD, page 55).

Scoring

Method for scoring varies by version. For the $HDRS_{17}$, a score of 0–7 is generally accepted to be within the normal range (or in clinical remission), while a score of 20 or higher (indicating at least moderate severity) is usually required for entry into a clinical trial.

Versions

The scale has been translated into a number of languages including French, German, Italian, Thai, and Turkish. As well, there is an Interactive Voice Response version (IVR), a Seasonal Affective Disorder version (SIGH-SAD, see page 55), and a Structured Interview Version (HDS-SIV). Numerous versions with varying lengths include the HDRS17, HDRS21, HDRS29, HDRS8, HDRS6, HDRS24, and HDRS7 (see page 30).

Additional references

Hamilton M. Development of a rating scale for primary depressive illness. Br J Soc Clin Psychol 1967; 6(4):278-96.

Williams JB. A structured interview guide for the Hamilton Depression Rating Scale. Arch Gen Psychiatry 1988; 45(8):742-7.

Address for correspondence

The HDRS is in the public domain.

Hamilton Depression Rating Scale (HDRS)

PLEASE COMPLETE THE SCALE BASED ON A STRUCTURED INTERVIEW

Instructions: for each item select the one "cue" which best characterizes the patient. Be sure to record the answers in the appropriate spaces (positions 0 through 4).

1 **DEPRESSED MOOD** *(sadness, hopeless, helpless, worthless)*
- 0 |__| Absent.
- 1 |__| These feeling states indicated only on questioning.
- 2 |__| These feeling states spontaneously reported verbally.
- 3 |_| Communicates feeling states non-verbally, i.e. through facial expression, posture, voice and tendency to weep.
- 4 |_| Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication.

2 FEELINGS OF GUILT
- 0 |__| Absent.
- 1 |__| Self reproach, feels he/she has let people down.
- 2 |_| Ideas of guilt or rumination over past errors or sinful deeds.
- 3 |__| Present illness is a punishment. Delusions of guilt.
- 4 |_| Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations.

3 SUICIDE

0 |__| Absent.
1 |__| Feels life is not worth living.
2 |_| Wishes he/she were dead or any thoughts of possible death to self.
3 |__| Ideas or gestures of suicide.
4 |__| Attempts at suicide (any serious attempt rate 4).

4 INSOMNIA: EARLY IN THE NIGHT

0 |__| No difficulty falling asleep.
1 |_| Complains of occasional difficulty falling asleep, i.e. more than ½ hour.
2 |__| Complains of nightly difficulty falling asleep.

5 INSOMNIA: MIDDLE OF THE NIGHT

0 |__| No difficulty.
1 |_| Patient complains of being restless and disturbed during the night.
2 |__| Waking during the night – any getting out of bed rates 2 (except for purposes of voiding).

6 INSOMNIA: EARLY HOURS OF THE MORNING

0 |__| No difficulty.
1 |_| Waking in early hours of the morning but goes back to sleep.
2 |__| Unable to fall asleep again if he/she gets out of bed.

7 WORK AND ACTIVITIES

0 |__| No difficulty.
1 |_| Thoughts and feelings of incapacity, fatigue or weakness related to activities, work or hobbies.
2 |_| Loss of interest in activity, hobbies or work – either directly reported by the patient or indirect in listlessness, indecision and vacillation (feels he/she has to push self to work or activities).
3 |__| Decrease in actual time spent in activities or decrease in productivity. Rate 3 if the patient does not spend at least three hours a day in activities (job or hobbies) excluding routine chores.
4 |_| Stopped working because of present illness. Rate 4 if patient engages in no activities except routine chores, or if patient fails to perform routine chores unassisted.

8 RETARDATION (slowness of thought and speech, impaired ability to concentrate, decreased motor activity)

0 |__| Normal speech and thought.
1 |__| Slight retardation during the interview.
2 |__| Obvious retardation during the interview.
3 |__| Interview difficult.
4 |__| Complete stupor.

9 AGITATION

0 |__| None.
1 |__| Fidgetiness.
2 |__| Playing with hands, hair, etc.
3 |__| Moving about, can't sit still.
4 |__| Hand wringing, nail biting, hair-pulling, biting of lips.

10 ANXIETY PSYCHIC

0 |__| No difficulty.
1 |__| Subjective tension and irritability.
2 |__| Worrying about minor matters.
3 |__| Apprehensive attitude apparent in face or speech.
4 |__| Fears expressed without questioning.

11 ANXIETY SOMATIC (physiological concomitants of anxiety) such as:

gastro-intestinal – dry mouth, wind, indigestion, diarrhea, cramps, belching
cardio-vascular – palpitations, headaches
respiratory – hyperventilation, sighing
urinary frequency
sweating

0 |__| Absent.
1 |__| Mild.
2 |__| Moderate.
3 |__| Severe.
4 |__| Incapacitating.

12 SOMATIC SYMPTOMS GASTRO-INTESTINAL

0 |__| None.
1 |_| Loss of appetite but eating without staff encouragement. Heavy feelings in abdomen.
2 |_| Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for gastro-intestinal symptoms.

13 GENERAL SOMATIC SYMPTOMS

0 |__| None.
1 |_| Heaviness in limbs, back or head. Backaches, headaches, muscle aches. Loss of energy and fatigability.
2 |__| Any clear-cut symptom rates 2.

14 GENITAL SYMPTOMS (symptoms such as loss of libido, menstrual disturbances)

0 |__| Absent.
1 |__| Mild.
2 |__| Severe.

15 HYPOCHONDRIASIS

0 |__| Not present.
1 |__| Self-absorption (bodily).
2 |__| Preoccupation with health.
3 |__| Frequent complaints, requests for help, etc.
4 |__| Hypochondriacal delusions.

16* LOSS OF WEIGHT *(RATE EITHER a OR b)

a) According to the patient:	**b) According to weekly measurements:**
0 |__| No weight loss.	0 |__| Less than 1 lb weight loss in week.
1 |__| Probable weight loss associated with present illness.	1 |_| Greater than 1 lb weight loss in week.
2 |_| Definite (according to patient) weight loss.	2 |_| Greater than 2 lb weight loss in week.
3 |__| Not assessed.	3 |_| Not assessed.

17 INSIGHT

0 |__| Acknowledges being depressed and ill.
1 |_| Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc.
2 |__| Denies being ill at all.

Total score: |__|__|

This scale is in the public domain.

Hamilton Anxiety Rating Scale (HAM-A)

Reference: **Hamilton M.The assessment of anxiety states by rating. Br J Med Psychol 1959; 32:50–55.**

Rating Clinician-rated

Administration time 10–15 minutes

Main purpose To assess the severity of symptoms of anxiety

Population Adults, adolescents and children

Commentary

The HAM-A was one of the first rating scales developed to measure the severity of anxiety symptoms, and is still widely used today in both clinical and research settings. The scale consists of 14 items, each defined by a series of symptoms, and measures both psychic anxiety (mental agitation and psychological distress) and somatic anxiety (physical complaints related to anxiety). Although the HAM-A remains widely used as an outcome measure in clinical trials, it has been criticized for its sometimes poor ability to discriminate between anxiolytic and antidepressant effects, and somatic anxiety versus somatic side effects. The HAM-A does not provide any standardized probe questions. Despite this, the reported levels of inter-rater reliability for the scale appear to be acceptable.

Scoring

Each item is scored on a scale of 0 (not present) to 4 (severe), with a total score range of 0–56, where <17 indicates mild severity, 18–24 mild to moderate severity and 25–30 moderate to severe.

Versions

The scale has been translated into: Cantonese for China, French and Spanish. An IVR version of the scale is available from Healthcare Technology Systems.

Additional references

Maier W, Buller R, Philipp M, Heuser I. The Hamilton Anxiety Scale: reliability, validity and sensitivity to change in anxiety and depressive disorders. J Affect Disord 1988;14(1):61–8.

Borkovec T and Costello E. Efficacy of applied relaxation and cognitive behavioral therapy in the treatment of generalized anxiety disorder. J Clin Consult Psychol 1993; 61(4):611–19

Address for correspondence

The HAM-A is in the public domain.

Hamilton Anxiety Rating Scale (HAM-A)

Below is a list of phrases that describe certain feeling that people have. Rate the patients by finding the answer which best describes the extent to which he/she has these conditions. Select one of the five responses for each of the fourteen questions.

0 = Not present, 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Very severe.

1 Anxious mood [0] [1] [2] [3] [4]

Worries, anticipation of the worst, fearful anticipation, irritability.

2 Tension [0] [1] [2] [3] [4]

Feelings of tension, fatigability, startle response, moved to tears easily, trembling, feelings of restlessness, inability to relax.

3 Fears [0] [1] [2] [3] [4]

Of dark, of strangers, of being left alone, of animals, of traffic, of crowds.

4 Insomnia [0] [1] [2] [3] [4]

Difficulty in falling asleep, broken sleep, unsatisfying sleep and fatigue on waking, dreams, nightmares, night terrors.

5 Intellectual [0] [1] [2] [3] [4]

Difficulty in concentration, poor memory.

6 Depressed mood [0] [1] [2] [3] [4]

Loss of interest, lack of pleasure in hobbies, depression, early waking, diurnal swing.

7 Somatic (muscular) [0] [1] [2] [3] [4]

Pains and aches, twitching, stiffness, myoclonic jerks, grinding of teeth, unsteady voice, increased muscular tone.

8 Somatic (sensory) [0] [1] [2] [3] [4]

Tinnitus, blurring of vision, hot and cold flushes, feelings of weakness, pricking sensation.

9 Cardiovascular symptoms [0] [1] [2] [3] [4]

Tachycardia, palpitations, pain in chest, throbbing of vessels, fainting feelings, missing beat.

10 Respiratory symptoms [0] [1] [2] [3] [4]

Pressure or constriction in chest, choking feelings, sighing, dyspnea.

11 Gastrointestinal symptoms [0] [1] [2] [3] [4]

Difficulty in swallowing, wind abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, borborygmi, looseness of bowels, loss of weight, constipation.

12 Genitourinary symptoms [0] [1] [2] [3] [4]

Frequency of micturition, urgency of micturition, amenorrhea, menorrhagia, development of frigidity, premature ejaculation, loss of libido, impotence.

13 Autonomic symptoms [0] [1] [2] [3] [4]

Dry mouth, flushing, pallor, tendency to sweat, giddiness, tension headache, raising of hair.

14 Behavior at interview [0] [1] [2] [3] [4]

Fidgeting, restlessness or pacing, tremor of hands, furrowed brow, strained face, sighing or rapid respiration, facial pallor, swallowing, etc.

Name:_____ Date: _____

Pittsburgh Sleep Quality Index (PSQI)

Instructions: The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. **Please answer all questions.**

1. During the past month, what time have you usually gone to bed at night? _____
2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night? _____
3. During the past month, what time have you usually gotten up in the morning? _____
4. During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spent in bed.) _____

5. During the past month, how often have you had trouble sleeping because you…	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
a. Cannot get to sleep within 30 minutes				
b. Wake up in the middle of the night or early morning				
c. Have to get up to use the bathroom				
d. Cannot breathe comfortably				
e. Cough or snore loudly				
f. Feel too cold				
g. Feel too hot				
h. Have bad dreams				
i. Have pain				
j. Other reason(s), please describe:				
6. During the past month, how often have you taken medicine to help you sleep (prescribed or "over the counter")?				
7. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?				
	No problem at all	Only a very slight problem	Somewhat of a problem	A very big problem
8. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?				
	Very good	Fairly good	Fairly bad	Very bad
9. During the past month, how would you rate your sleep quality overall?				

	No bed partner or room mate	Partner/room mate in other room	Partner in same room but not same bed	Partner in same bed
10. Do you have a bed partner or room mate?				
	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
If you have a room mate or bed partner, ask him/her how often in the past month you have had:				
a. Loud snoring				
b. Long pauses between breaths while asleep				
c. Legs twitching or jerking while you sleep				
d. Episodes of disorientation or confusion during sleep				
e. Other restlessness while you sleep, please describe:				

Scoring the PSQI

The order of the PSQI items has been modified from the original order in order to fit the first 9 items (which are the only items that contribute to the total score) on a single page. Item 10, which is the second page of the scale, does not contribute to the PSQI score.

In scoring the PSQI, seven component scores are derived, each scored 0 (no difficulty) to 3 (severe difficulty). The component scores are summed to produce a global score (range 0 to 21). Higher scores indicate worse sleep quality.

Component 1: Subjective sleep quality—question 9

Response to Q9	Component 1 score
Very good	0
Fairly good	1
Fairly bad	2
Very bad	3

Component 1 score:_____

Component 2: Sleep latency—questions 2 and 5a

Response to Q2	Component 2/Q2 subscore
≤ 15 minutes	0
16-30 minutes	1
31-60 minutes	2
> 60 minutes	3

Response to Q5a	Component 2/Q5a subscore
Not during past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3

Sum of Q2 and Q5a subscores	Component 2 score
0	0
1-2	1
3-4	2
5-6	3

Component 2 score:_____

Component 3: Sleep duration—question 4

Response to Q4	Component 3 score
> 7 hours	0
6-7 hours	1
5-6 hours	2
< 5 hours	3

Component 3 score:_____

Component 4: Sleep efficiency—questions 1, 3, and 4

Sleep efficiency = (# hours slept/# hours in bed) X 100%

hours slept—question 4

hours in bed—calculated from responses to questions 1 and 3

Sleep efficiency	Component 4 score
> 85%	0
75-84%	1
65-74%	2
< 65%	3

Component 4 score:_____

Component 5: Sleep disturbance—questions 5b-5j

Questions 5b to 5j should be scored as follows:

Not during past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3

Sum of 5b to 5j scores	Component 5 score
0	0
1-9	1
10-18	2
19-27	3

Component 5 score:_____

Component 6: Use of sleep medication—question 6

Response to Q6	Component 6 score
Not during past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3

Component 6 score:_____

Component 7: Daytime dysfunction—questions 7 and 8

Response to Q7	Component 7/Q7 subscore
Not during past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3

Response to Q8	Component 7/Q8 subscore
No problem at all	0
Only a very slight problem	1
Somewhat of a problem	2
A very big problem	3

Sum of Q7 and Q8 subscores	Component 7 score
0	0
1-2	1
3-4	2
5-6	3

Component 7 score:_____

Global PSQI Score: Sum of seven component scores:_____

Copyright notice: The Pittsburgh Sleep Quality Index (PSQI) is copyrighted by Daniel J. Buysse, M.D. Permission has been granted to reproduce the scale on this website for clinicians to use in their practice and for researchers to use in non-industry studies. For other uses of the scale, the owner of the copyright should be contacted.

Citation: Buysse, DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ: The Pittsburgh Sleep Quality Index (PSQI): A new instrument for psychiatric research and practice. Psychiatry Research 28:193-213, 1989

Appendix 3: PCOSQ

Instructions: This questionnaire is designed for women with Polycystic Ovary Syndrome. In the questionnaire, we will refer to the Polycystic Ovary Syndrome by its initials: PCOS. The questions concern your health and health-related issues. Please respond to each question by checking the box with the rating that best reflects how you feel. For each question, you have seven rating options. Option 1 represents the greatest possible impairment, while Option 7 represents the least impairment. Choose only one option for each question. There is no right or wrong answer. Just choose the option that is closest to how you feel.

Date:

Study No:

Interview No: 1 / 2 PCOSQ

To what extent have you felt that growth of visible hair on your chin has been a problem for you during the **last two weeks:**

	A severe problem	A major problem	A moderate problem	Some problem	A little problem	Hardly any problem	No problem
Q1. Growth of visible hair on chin?	☐	☐	☐	☐	☐	☐	☐

During **the past two weeks,** how much of the time have you felt?

	All the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Hardly any of the time	None of the time
Q2. Depressed as a result of having PCOS?	☐	☐	☐	☐	☐	☐	☐
Q3. Concerned about being overweight?	☐	☐	☐	☐	☐	☐	☐
Q4. Easily tired?	☐	☐	☐	☐	☐	☐	☐

Q5. Concerned with infertility problems?	☐	☐	☐	☐	☐	☐	☐
Q6. Moody as a result of having PCOS?	☐	☐	☐	☐	☐	☐	☐

In addition to your last menstruation, how much were the following issues a problem for you?

	A severe problem	A major problem	A moderate problem	Some problem	A little problem	Hardly any problem	No problem
Q7. Headaches?	☐	☐	☐	☐	☐	☐	☐
Q8. Irregular menstrual periods?	☐	☐	☐	☐	☐	☐	☐

To what extent has growth of visible hair on your upper lip been a problem for you **the last two weeks?**

	A severe problem	A major problem	A moderate problem	Some problem	A little problem	Hardly any problem	No problem
Q9. Growth of visible hair on upper lip?	☐	☐	☐	☐	☐	☐	☐

During the **past two weeks,** how much of the time have you**:**

	All the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Hardly any of the time	None of the time
Q10. Had trouble dealing with your weight?	☐	☐	☐	☐	☐	☐	☐
Q11. Had low self-esteem as a result of having PCOS?	☐	☐	☐	☐	☐	☐	☐
Q12. Felt frustration in trying to lose weight?	☐	☐	☐	☐	☐	☐	☐
Q13. Felt afraid of not being able to have children?	☐	☐	☐	☐	☐	☐	☐
Q14. Felt frightened of getting cancer?	☐	☐	☐	☐	☐	☐	☐

Over the **last two weeks** to what extent the following issues have been a problem for you:

	A severe problem	A major problem	A moderate problem	Some problem	A little problem	Hardly any problem	No problem
Q15. Growth of visible hair on your face?	☐	☐	☐	☐	☐	☐	☐
Q16. Embarrassment about excessive body hair?	☐	☐	☐	☐	☐	☐	☐

During the **past two weeks** how much of the time have you been:

	All the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Hardly any of the time	None of the time
Q17. Worried about having PCOS?	☐	☐	☐	☐	☐	☐	☐
Q18. Self-conscious as a result of having PCOS?	☐	☐	☐	☐	☐	☐	☐

In relation to **<u>your last menstruation</u>**, how much the following issues were a problem for you:

	A severe problem	A major problem	A moderate problem	Some problem	A little problem	Hardly any problem	No problem
Q19. Abdominal bloating?	☐	☐	☐	☐	☐	☐	☐
Q20. Late menstrual period?	☐	☐	☐	☐	☐	☐	☐
Q21. Menstrual cramps?	☐	☐	☐	☐	☐	☐	☐

How much of the time during the **<u>last two weeks</u>** did you**:**

	All the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Hardly any of the time	None of the time
Q22. Feel like you are not sexy because of being overweight?	☐	☐	☐	☐	☐	☐	☐

Q23. Feel a lack of control over the situation with PCOS?	☐	☐	☐	☐	☐	☐	☐
Q24. Have difficulties staying at your ideal weight?	☐	☐	☐	☐	☐	☐	☐
Q25. Feel sad because of infertility problems?	☐	☐	☐	☐	☐	☐	☐

To what extent has growth of visible body hair been a problem for you the **last two weeks?**

	A severe problem	A major problem	A moderate problem	Some problem	A little problem	Hardly any problem	No problem
Q26. Growth of visible body hair?	☐	☐	☐	☐	☐	☐	☐

THIS QUESTIONNAIRE WAS DEVELOPED BY AND OBTAINED FROM:

L. Cronin, G. Guyatt, L. Griffith, E. Wong, R. Azziz, W. Futterweit, D. Cook, A. Dunaif. Development of a Health-Related Quality-of-Life Questionnaire (PCOSQ) for Women with Polycystic Ovary Syndrome (PCOS) Journal of Clinical Endocrinology and Metabolism 1998;83(6):1976-1986*

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INFORMED PATIENT CONSENT

Date: _____

I.....D/o, W/o, S/o..... .....am willing to participate in the study **"EFFECT OF CBT ON PSYCHOLOGICAL MORBIDITY, QUALITY OF LIFE AND SLEEP DISTURBANCE IN WOMEN WITH POLYCYSTIC OVARIAN SYNDROME; PRE AND POST STUDY"** The procedure with its complications has been explained to me in local vernacular language. I have fully understood that no special tests and extra expenditure in any form, merely for the purpose of dissertation is being carried out. I am free to opt out the study any time without assigning any reason.

....

Signature of the Witness Signature of the patient

Name:

Signature of Candidate **Signature of Supervisor**

मरीज अनुमति फार्म

तिथि _____

मैं _____ पत्नी/पुत्र/पुत्री _____

निवासी _____

इस शोधकार्य **"EFFECT OF CBT ON PSYCHOLOGICAL MORBIDITY, QUALITY OF LIFE AND SLEEP DISTURBANCE IN WOMEN WITH POLYCYSTIC OVARIAN SYNDROME; PRE AND POST STUDY"** में भाग लेने के लिए सहमत हूँ। मैं इस शोधकार्य में भाग लेने के लिए अपनी स्वेच्छा से तैयार हूँ। मैं पुष्टि करता/करती हूँ की यह स्वीकृति देने के लिए मुझे कोई आर्थिक प्रलोभन नहीं दिया गया और न ही दबाव डाला गया है। मुझे इस शोधकार्य का उद्देश्य स्पष्ट कर दिया गया है और मुझे यह विश्वास है की यह विज्ञान और मानवता के लाभ के लिए है। मुझे इस शोधकार्य में होने वाले जोखिम के बारे में समझा दिया गया है और मेरी समझ में यह जोखिम बहुत मामुली है।

मैं इस शोधकार्य में भाग लेने के सम्बन्ध में किसी भी समय अपनी अस्वीकृति व्यक्त कर सकता/सकती हूँ और मेरे अस्वीकृति व्यक्त करने का मेरे इलाज पर कोई प्रभाव नहीं पड़ेगा।

_____ _____

गवाह के हस्ताक्षर रोगी के हस्ताक्षर/अंगूठे का निशान

नाम: नाम:

_____

अन्वेषक के हस्ताक्षर

_____

विद्यार्थी के हस्ताक्षर

ਮਰੀਜ਼ ਰਜ਼ਾਮੰਦੀ ਫਾਰਮ

ਮਿਤੀ_____

ਮੈ_____ਪਤਨੀ/ਪੁੱਤਰ/ਪੁੱਤਰੀ_____

ਵਾਸੀ_____ _____

"EFFECT OF CBT ON PSYCHOLOGICAL MORBIDITY, QUALITY OF LIFE AND SLEEP DISTURBANCE IN WOMEN WITH POLYCYSTIC OVARIAN SYNDROME; PRE AND POST STUDY" ਤੇ ਚਲ ਰਹੀ ਖੋਜ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਰਜ਼ਾਮੰਦ ਹਾਂ ।ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਮੈ ਆਪਣੀ ਮਰਜ਼ੀ ਨਾਲ ਤਿਆਰ ਹਾਂ ।ਮੈ ਇਹ ਦਸਣਾ ਚਾਹੁੰਦਾ ਹਾਂ/ ਚਾਹੁੰਦੀ ਹਾਂ ਕੇ ਇਹ ਰਜ਼ਾਮੰਦੀ ਦੇਣ ਵਾਸਤੇ ਮੈਨੂ ਕਿਸੇ ਵੀ ਤਰਾਂ ਦਾ ਲੋਭ-ਲਾਲਚ ਨਹੀ ਦਿੱਤਾ ਗਿਆ ਅਤੇ ਨਾ ਹੀ ਕੋਈ ਦਬਾ ਪਾਇਆ ਗਿਆ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਦਾ ਮਨੋਰਥ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਭਰੋਸਾ ਦਵਾਇਆ ਗਿਆ ਹੈ ਕੇ ਇਹ ਖੋਜ ਵਿਗਿਆਨ ਅਤੇ ਮਾਨਵਤਾ ਦੀ ਭਲਾਈ ਲਈ ਹੈ ।ਮੈਨੂ ਇਸ ਖੋਜ ਵਿਚ ਹੋਣ ਵਾਲੇ ਖਤਰੇ ਬਾਰੇ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਯਕੀਨ ਹੈ ਕੇ ਇਹ ਖਤਰਾ ਬਹੁਤ ਮਾਮੂਲੀ ਹੈ ।ਮੈਨੂ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਦਾ ਢੰਗ – ਤਰੀਕਾ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ।

ਮੈ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਬਾਰੇ ਆਪਣੀ ਰਜ਼ਾਮੰਦੀ ਕਿਸੇ ਵੀ ਸਮੇ ਵਾਪਸ ਲੈ ਸਕਦਾ ਹਾਂ/ ਸਕਦੀ ਹਾਂ ਅਤੇ ਮੇਰੀ ਰਜ਼ਾਮੰਦੀ ਵਾਪਸ ਲੈਣ ਦਾ ਮੇਰੇ ਇਲਾਜ ਤੇ ਕੋਈ ਅਸਰ ਨਹੀ ਹੋਵੇਗਾ।

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ਗਵਾਹ ਦੇ ਹਸਤਾਖਰ

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ਮਰੀਜ਼ ਦੇ ਹਸਤਾਖਰ

ਮਿਤੀ_____

ਪਤਾ _____

ਮਿਤੀ_____

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ਨਿਰੀਖਕ ਦੇ ਹਸਤਾਖਰ

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ਸਿਖਿਆਰਥੀ ਦੇ ਹਸਤਾਖਰ